

UWI2013-00-01 - ENHANCED PERSON: DATA DICTIONARY

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Document Summary

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UWI2013-00-01 - Enhanced Person: Data Dictionary

Section 1: Identifiers

Variable	Label	Description	Format Text
sequence_no_	Patient ID		Numeric

Section 2: Study Wide

Variable	Label	Description	Format Text
institution	Registering Institution		1="MA017" 2="MN022" 3="TX273" 4="WI020"
rand_dt	Randomization Date		SAS Date .R="Participant Not Randomized"
rand_num	Randomization Number		Numeric .R="Participant Not Randomized"
treatment	Treatment		.F="No Form" .R="Participant Not Randomized" 1="PFE" 2="Placebo"
visit_dt	Visit Date		SAS Date

Section 3: Registration

Variable	Label	Description	Format Text
reg_age	Age At Registration - [Registration]		Numeric
reg_consent_dt	Date Study Informed Consent Signed - [Registration]		SAS Date
reg_dt	Date Of Registration - [Registration]		SAS Date
reg_elig_crit	Does The Participant Satisfy All Of The Eligibility Criteria - [Registration]		0="No" 1="Yes"
reg_ethnicity	Ethnicity - [Registration]		0="Not Hispanic or Latino" 1="Hispanic or Latino"
reg_gender	Gender - [Registration]		1="Male"
reg_race	Race - [Registration]		1="White" 2="Black or African American"

Section 4: Screening

Variable	Label	Description	Format Text
screening_comments	Comments - [Screening]		Char, 615
screening_criteria	Does The Participant Meet All Screening Criteria? - [Screening]		0="No" 1="Yes"
screening_dt	Screen Date - [Screening]		SAS Date
screening_refer	Who Referred Participant - [Screening]		1="Health Care Provider" 2="Physician"
screening_study	How Did Participant Find Out About The Study - [Screening]		1="Nurse" 2="Physician"

Section 5: Exclusion Criteria

Variable	Label	Description	Format Text
exc_5a_reductase	Participant Is Taking 5-A-Reductase Inhibitors. - [Exclusion Criteria]	4. Participant is taking or is planning to take 5-a-reductase inhibitors or has taken 5-a-reductase inhibitors within 6 months of the baseline study visit.	0="No"
exc_allergic_history	Participant Has A History Of Allergic Reaction To Pomegranate Fruit Extract - [Exclusion Criteria]	7. Participant has a history of allergic reactions attributed to compounds of similar chemical or biologic composition to Pomegranate Fruit Extract.	0="No"
exc_carbamazepine	Participant Is Taking Carbamazepine - [Exclusion Criteria]	5. Participant is taking carbamazepine (Tegretol).	0="No"
exc_cardiac_event	Participant Has Had A Significant Cardiac Event(s) - [Exclusion Criteria]	9. Participant has had a significant cardiac event(s) within the 12 months prior to registration, such as episode(s) of symptomatic congestive heart failure; myocardial infarction; unstable angina pectoris or persistent, stable angina pectoris; or cardiac arrhythmia requiring medication.	0="No"
exc_intercurrent_ill	Participant Has Uncontrolled Intercurrent Illness - [Exclusion Criteria]	8. Participant has uncontrolled intercurrent illness including, but not limited to, ongoing or active infection, or psychiatric illness/social situations that would limit compliance with study requirements.	0="No" 1="Yes"
exc_nsaid	Participant Is Taking NSAIDs - [Exclusion Criteria]	10. Participant Is Taking NSAIDs On A Regularly Scheduled Basis, Except For Cardioprotective Aspirin (81 Mg). Participants May Take Acetaminophen For Pain.	.V="Wrong Form Version" 0="No"
exc_other_cancer	Participant Has Evidence Of Other Cancer(s) - [Exclusion Criteria]	2. Participant has evidence of other cancer(s) (excluding non-melanoma skin cancer) within the past 5 years.	0="No"
exc_pelvic_radiation	Participant Has Had Prior Pelvic Radiation - [Exclusion Criteria]	3. Participant has had pelvic radiation, for any reason.	0="No"

Variable	Label	Description	Format Text
exc_receiving_other	Participant Is Receiving Other Investigational Agents - [Exclusion Criteria]	6. Participant is receiving other investigational agents.	0="No"
exc_surgery_prostate	The Participant Has Had Surgery To The Prostate - [Exclusion Criteria]	1. Participant has had surgery to the prostate within 30 days of baseline procedure (biopsies are not considered surgeries).	0="No"

Section 6: Inclusion Criteria

Variable	Label	Description	Format Text
inc_consent	The Participant Has A Written Informed Consent Document - [Inclusion Criteria]	8. The participant is able to understand, and willing to sign, a written informed consent document.	1="Yes"
inc_ecog_perform	The Participant Has An ECOG Performance Status Of < Or = 1. - [Inclusion Criteria]	4. The participant has an ECOG performance status of < 1.	1="Yes"
inc_has_biopsy	The Participant Has Valid Biopsies - [Inclusion Criteria]	1. Participant must have had a standard-of-care biopsy within 13 months of the baseline study visit and must have been diagnosed with low-grade, clinically localized prostate cancer: Gleason Score <= 3+3 with a PSA at baseline <10ng/ml in participants <70 years of age, OR Gleason Score <3+4 with a PSA at baseline <=15ng/ml in participants >=70 years of age). Participant is able and willing to undergo AS with PSA monitoring and a scheduled biopsy performed at the end of the study.	0="No" 1="Yes"
inc_medic_approve	The Participant Agrees To Use Birth Control Or Abstain - [Inclusion Criteria]	6. The participant agrees to use a medically-approved method of birth control or abstinence if his sexual partner is of child-bearing potential.	.N="Not Applicable" 1="Yes"
inc_no_pomegranate	The Participant Agrees To Forego Foods Containing Pomegranate - [Inclusion Criteria]	7. The participant agrees to forego foods, beverages and supplements containing pomegranate for the duration of the study.	1="Yes"

Variable	Label	Description	Format Text
inc_no_treatment	Participant Is Not Planning On Receiving Concurrent Treatment For Prostate Cancer - [Inclusion Criteria]	2. Participant is not planning on receiving concurrent treatment (hormonal, radiation or systemic chemotherapy) for prostate cancer during the study period (unless the participant demonstrates clinical evidence of prostate cancer progression such as symptoms, physical exam findings, a rapidly increasing PSA, or radiologic findings which confirm disease progression).	0="No" 1="Yes"
inc_normal_organ	The Participant Has Normal Organ And Marrow Function - [Inclusion Criteria]	5. The participant has normal organ and marrow function as follows: WBC > 3,000/mm ³ AST < 1.5 x ULN Platelets >100,000/mm ³ ALT < 1.5 x ULN Hemoglobin > 10g/dL Serum Creatinine within 1.5 x ULN Total bilirubin < 1.5 x ULN Sodium 135-144 mmol/L (inclusive) Alkaline phosphatase < 1.5 x ULN Potassium 3.2-4.8 mmol/L (inclusive)	0="No" 1="Yes"
inc_twentyone_years	Participant Is >= 21 Years Of Age - [Inclusion Criteria]	3. Participant is > 21 years of age.	1="Yes"

Section 7: Medical History

Variable	Label	Description	Format Text
medhis_abdomen_abn	Has Abnormality? - Abdomen - [Medical History]		.F="No Form" .R="Participant Not Randomized" 0="No" 1="Yes"
medhis_appear_abn	Has Abnormality? - Appearance - [Medical History]		.F="No Form" .R="Participant Not Randomized" 0="No"
medhis_breasts_abn	Has Abnormality? - Breasts - [Medical History]		.F="No Form" .R="Participant Not Randomized" 0="No" 9="Not Assessed"
medhis_chest_abn	Has Abnormality? - Chest - [Medical History]		.F="No Form" .R="Participant Not Randomized" 0="No"
medhis_genit_abn	Has Abnormality? - Genitals - [Medical History]		.F="No Form" .R="Participant Not Randomized" 0="No" 1="Yes" 9="Not Assessed"
medhis_heart_abn	Has Abnormality? - Heart - [Medical History]		.F="No Form" .R="Participant Not Randomized" 0="No"
medhis_heent_abn	Has Abnormality? - H/E/E/N/T - [Medical History]		.F="No Form" .R="Participant Not Randomized" 0="No" 1="Yes" 9="Not Assessed"
medhis_lungs_abn	Has Abnormality? - Lung - [Medical History]		.F="No Form" .R="Participant Not Randomized" 0="No"
medhis_lymph_abn	Has Abnormality? - Lymph Nodes- [Medical History]		.F="No Form" .R="Participant Not Randomized" 0="No" 9="Not Assessed"
medhis_musc_abn	Has Abnormality? - Musculoskeletal - [Medical History]		.F="No Form" .R="Participant Not Randomized" 0="No" 9="Not Assessed"
medhis_neur_abn	Has Abnormality? - Neurological - [Medical History]		.F="No Form" .R="Participant Not Randomized" 0="No" 1="Yes" 9="Not Assessed"
medhis_pelvis_abn	Has Abnormality? - Pelvis - [Medical History]		.F="No Form" .R="Participant Not Randomized" 0="No" 9="Not Assessed"

Variable	Label	Description	Format Text
medhis_pros_abn	Has Abnormality? - Prostate - [Medical History]		.F="No Form" .R="Participant Not Randomized" 0="No" 1="Yes" 9="Not Assessed"
medhis_rectal_abn	Has Abnormality? - Rectal - [Medical History]		.F="No Form" .R="Participant Not Randomized" 0="No" 9="Not Assessed"
medhis_skin_abn	Has Abnormality? - Skin - [Medical History]		.F="No Form" .R="Participant Not Randomized" 0="No" 1="Yes" 9="Not Assessed"
medhis_thyd_abn	Has Abnormality? - Thyroid - [Medical History]		.F="No Form" .R="Participant Not Randomized" 0="No" 9="Not Assessed"
medhis_vasc_abn	Has Abnormality? - Vascular - [Medical History]		.F="No Form" .R="Participant Not Randomized" 0="No" 9="Not Assessed"

Section 8: Physical Exam

Variable	Label	Description	Format Text
physexam_abdomen_abn_v0-4	Has Body System Abnormality At Visit [X]? - Abdomen - [Physical Exam]		.F="No Form" .R="Participant Not Randomized" 0="No" 1="Yes" 9="Not Assessed"
physexam_abdomen_comment_v0-4	Body System Comments At Visit [X] - Abdomen - [Physical Exam]		Char, 103
physexam_appearance_abn_v0-4	Has Body System Abnormality At Visit [X]? - Appearance - [Physical Exam]		.F="No Form" .R="Participant Not Randomized" 0="No" 1="Yes" 9="Not Assessed"
physexam_appearance_comment_v0-4	Body System Comments At Visit [X] - Appearance - [Physical Exam]		Char, 103
physexam_body_system_none_v0-4	Check Here If NO Body Systems Were Examined At Visit [X] - [Physical Exam]		.F="No Form" .M="Missing" 1="Not Examined"
physexam_body_system_none_v4_2nd	Check Here If NO Body Systems Were Examined At Visit 4 (End Of Study) - 2nd Examination - [Physical Exam]		.M="Missing" .N="Not Applicable"
physexam_bp_diastolic_NO_v0-4	Diastolic Pressure (mm Hg) Not Obtained, At Visit [X] - [Physical Exam]		.F="No Form" .M="Missing" 1="Not Done"
physexam_bp_diastolic_NO_v4_2nd	Diastolic Pressure (mm Hg) Not Obtained, At Visit 4 (End Of Study) - 2nd Examination - [Physical Exam]		.M="Missing" .N="Not Applicable"
physexam_bp_diastolic_v0-4	Diastolic Pressure (mm Hg) At Visit [X] - [Physical Exam]		Numeric .F="No Form" .M="Missing"
physexam_bp_diastolic_v4_2nd	Diastolic Pressure (mm Hg) At Visit 4 (End Of Study) - 2nd Examination - [Physical Exam]		Numeric .N="Not Applicable"
physexam_bp_systolic_NO_v0-4	Systolic Pressure (mm Hg) Not Obtained, At Visit [X] - [Physical Exam]		.F="No Form" .M="Missing" 1="Not Done"
physexam_bp_systolic_NO_v4_2nd	Systolic Pressure (mm Hg) Not Obtained, At Visit 4 (End Of Study) - 2nd Examination - [Physical Exam]		.M="Missing" .N="Not Applicable"

Variable	Label	Description	Format Text
physexam_bp_systolic_v0-4	Systolic Pressure (mm Hg) At Visit [X] - [Physical Exam]		Numeric .F="No Form" .M="Missing"
physexam_bp_systolic_v4_2nd	Systolic Pressure (mm Hg) At Visit 4 (End Of Study) - 2nd Examination - [Physical Exam]		Numeric .N="Not Applicable"
physexamBreasts_abn_v0-4	Has Body System Abnormality At Visit [X]? - Breast - [Physical Exam]		.F="No Form" .R="Participant Not Randomized" 0="No" 9="Not Assessed"
physexamBreasts_comment_v0-4	Body System Comments At Visit [X] - Breast - [Physical Exam]		Char, 103
physexamChest_abn_v0-4	Has Body System Abnormality At Visit [X]? - Chest - [Physical Exam]		.F="No Form" .R="Participant Not Randomized" 0="No" 1="Yes" 9="Not Assessed"
physexamChest_comment_v0-4	Body System Comments At Visit [X] - Chest - [Physical Exam]		Char, 103
physexamExamination_dt_v0-4	Examination Date At Visit [X] - [Physical Exam]		SAS Date .F="No Form" .M="Missing"
physexamExamination_dt_v4_2nd	Examination Date At Visit 4 (End Of Study) - 2nd Examination - [Physical Exam]		Numeric .N="Not Applicable"
physexamExamination_ND_v0-4	Examination Not Done At Visit [X] - [Physical Exam]		.F="No Form" .M="Missing" 1="Not Done"
physexamExamination_ND_v4_2nd	Examination Not Done At Visit 4 (End Of Study) - 2nd Examination - [Physical Exam]		.M="Missing" .N="Not Applicable"
physexamGenit_abn_v0-4	Has Body System Abnormality At Visit [X]? - Genitalia - [Physical Exam]		.F="No Form" .R="Participant Not Randomized" 0="No" 1="Yes" 9="Not Assessed"
physexamGenit_comment_v0-4	Body System Comments At Visit [X] - Genitalia - [Physical Exam]		Char, 103
physexamHeart_abn_v0-4	Has Body System Abnormality At Visit [X]? - Heart - [Physical Exam]		.F="No Form" .R="Participant Not Randomized" 0="No" 1="Yes" 9="Not Assessed"
physexamHeart_comment_v0-4	Body System Comments At Visit [X] - Heart - [Physical Exam]		Char, 103

Variable	Label	Description	Format Text
physexam_heent_abn_v0-4	Has Body System Abnormality At Visit [X]? - H/E/E/N/T - [Physical Exam]		.F="No Form" .R="Participant Not Randomized" 0="No" 1="Yes" 9="Not Assessed"
physexam_heent_comment_v0-4	Body System Comments At Visit [X] - H/E/E/N/T - [Physical Exam]		Char, 103
physexam_height_NO_v0-4	Height At Visit [X] - [Physical Exam]		.F="No Form" .M="Missing" 1="Not Done"
physexam_height_NO_v4_2nd	Height Not Obtained At Visit 4 (End Of Study) - 2nd Examination - [Physical Exam]		.N="Not Applicable" 1="Not Done"
physexam_height_unit_v0-4	Height Units At Visit [X] - [Physical Exam]		.F="No Form" .M="Missing" 1="cm" 2="in"
physexam_height_unit_v4_2nd	Height Units At Visit 4 (End Of Study) - 2nd Examination - [Physical Exam]		.M="Missing" .N="Not Applicable"
physexam_height_v0-4	Height At Visit [X] - [Physical Exam]		Numeric .F="No Form" .M="Missing"
physexam_height_v4_2nd	Height At Visit 4 (End Of Study) - 2nd Examination - [Physical Exam]		Numeric .M="Missing" .N="Not Applicable"
physexam_lungs_abn_v0-4	Has Body System Abnormality At Visit [X]? - Lung - [Physical Exam]		.F="No Form" .R="Participant Not Randomized" 0="No" 9="Not Assessed"
physexam_lungs_comment_v0-4	Body System Comments At Visit [X] - Lung - [Physical Exam]		Char, 103
physexam_lymph_abn_v0-4	Has Body System Abnormality At Visit [X]? - Lymph Nodes - [Physical Exam]		.F="No Form" .R="Participant Not Randomized" 0="No" 1="Yes" 9="Not Assessed"
physexam_lymph_comment_v0-4	Body System Comments At Visit [X] - Lymph Nodes - [Physical Exam]		Char, 103
physexam_musc_abn_v0-4	Has Body System Abnormality At Visit [X]? - Musculoskeletal - [Physical Exam]		.F="No Form" .R="Participant Not Randomized" 0="No" 1="Yes" 9="Not Assessed"
physexam_musc_comment_v0-4	Body System Comments At Visit [X] - Musculoskeletal - [Physical Exam]		Char, 103

Variable	Label	Description	Format Text
physexam_neur_abn_v0-4	Has Body System Abnormality At Visit [X]? - Neurological - [Physical Exam]		.F="No Form" .R="Participant Not Randomized" 0="No" 1="Yes" 9="Not Assessed"
physexam_neur_comment_v0-4	Body System Comments At Visit [X] - Neurological - [Physical Exam]		Char, 103
physexam_pelvis_abn_v0-4	Has Body System Abnormality At Visit [X]? - Pelvis - [Physical Exam]		.F="No Form" .R="Participant Not Randomized" 0="No" 9="Not Assessed"
physexam_pelvis_comment_v0-4	Body System Comments At Visit [X] - Pelvis - [Physical Exam]		Char, 103
physexam_performance_stat_v0-4	Performance Status At Visit [X] - [Physical Exam]		.F="No Form" .M="Missing" .N="Not Applicable" 0="Fully Active, No Restriction"
physexam_performance_stat_v4_2nd	Performance Status At Visit 4 (End Of Study) - 2nd Examination - [Physical Exam]		.N="Not Applicable"
physexam_pros_abn_v0-4	Has Body System Abnormality At Visit [X]? - Prostate - [Physical Exam]		.F="No Form" .R="Participant Not Randomized" 0="No" 1="Yes" 9="Not Assessed"
physexam_pros_comment_v0-4	Body System Comments At Visit [X] - Prostate - [Physical Exam]		Char, 103
physexam_pulse_NO_v0-4	Pulse Not Obtained At Visit [X] - [Physical Exam]		.F="No Form" .M="Missing" 1="Not Done"
physexam_pulse_NO_v4_2nd	Pulse Not Obtained At Visit 4 (End Of Study) - 2nd Examination - [Physical Exam]		.M="Missing" .N="Not Applicable"
physexam_pulse_v0-4	Pulse Rate At Visit [X] - [Physical Exam]		Numeric .F="No Form" .M="Missing"
physexam_pulse_v4_2nd	Pulse Rate At Visit 4 (End Of Study) - 2nd Examination - [Physical Exam]		Numeric .N="Not Applicable"
physexam_rectal_abn_v0-4	Has Body System Abnormality At Visit [X]? - Rectal - [Physical Exam]		.F="No Form" .R="Participant Not Randomized" 0="No" 9="Not Assessed"
physexam_rectal_comment_v0-4	Body System Comments At Visit [X] - Rectal - [Physical Exam]		Char, 103

Variable	Label	Description	Format Text
physexam_respiration_NO_v0-4	Respiration Rate Not Obtained At Visit [X] - [Physical Exam]		.F="No Form" .M="Missing" 1="Not Done"
physexam_respiration_NO_v4_2nd	Respiration Rate Not Obtained At Visit 4 (End Of Study) - 2nd Examination - [Physical Exam]		.N="Not Applicable" 1="Not Done"
physexam_skin_abn_v0-4	Has Body System Abnormality At Visit [X]? - Skin - [Physical Exam]		.F="No Form" .R="Participant Not Randomized" 0="No" 1="Yes" 9="Not Assessed"
physexam_skin_comment_v0-4	Body System Comments At Visit [X] - Skin - [Physical Exam]		Char, 103
physexam_temperature_NO_v0-4	Temperature Not Obtained At Visit [X] - [Physical Exam]		.F="No Form" .M="Missing" 1="Not Done"
physexam_temperature_NO_v4_2nd	Temperature Not Obtained At Visit 4 (End Of Study) - 2nd Examination - [Physical Exam]		.M="Missing" .N="Not Applicable"
physexam_temperature_unit_v0-4	Temperature Units At Visit [X] - [Physical Exam]		.F="No Form" .M="Missing" 1="C" 2="F"
physexam_temperature_unit_v4_2nd	Temperature Units At Visit 4 (End Of Study) - 2nd Examination - [Physical Exam]		.N="Not Applicable" 2="F"
physexam_temperature_v0-4	Temperature At Visit [X] - [Physical Exam]		Numeric .F="No Form" .M="Missing"
physexam_temperature_v4_2nd	Temperature At Visit 4 (End Of Study) - [Physical Exam]		Numeric .N="Not Applicable"
physexam_thyroid_abn_v0-4	Has Body System Abnormality At Visit [X]? - Thyroid - [Physical Exam]		.F="No Form" .R="Participant Not Randomized" 0="No" 9="Not Assessed"
physexam_thyroid_comment_v0-4	Body System Comments At Visit [X] - Thyroid - [Physical Exam]		Char, 103
physexam_vascular_abn_v0-4	Has Body System Abnormality At Visit [X]? - Vascular - [Physical Exam]		.F="No Form" .R="Participant Not Randomized" 0="No" 9="Not Assessed"
physexam_vascular_comment_v0-4	Body System Comments At Visit [X] - Vascular - [Physical Exam]		Char, 103
physexam_weight_NO_v0-4	Weight Not Obtained At Visit [X] - [Physical Exam]		.F="No Form" .M="Missing" 1="Not Done"

Variable	Label	Description	Format Text
physexam_weight_NO_v4_2nd	Weight Not Obtained At Visit 4 (End Of Study) - 2nd Examination - [Physical Exam]		.M="Missing" .N="Not Applicable"
physexam_weight_unit_v0-4	Weight Units At Visit [X] - [Physical Exam]		.F="No Form" .M="Missing" 1="kg" 2="lb"
physexam_weight_unit_v4_2nd	Weight Units At Visit 4 (End Of Study) - 2nd Examination - [Physical Exam]		.N="Not Applicable" 2="lb"
physexam_weight_v0-4	Weight At Visit [X] - [Physical Exam]		Numeric .F="No Form" .M="Missing"
physexam_weight_v4_2nd	Weight At Visit 4 (End Of Study) - 2nd Examination - [Physical Exam]		Numeric .N="Not Applicable"

Section 9: Baseline Symptoms

Variable	Label	Description	Format Text
basesymptom_cnt	Number Of Symptoms - [Baseline Symptoms]		Numeric
basesymptom_comments1-4	Comments For Symptom [X] - [Baseline Symptoms]		Char, 409
basesymptom_description1-4	Symptom Description For Symptom [X] - [Baseline Symptoms]		Char, 80
basesymptom_grade1-4	Grade For Symptom [X] - [Baseline Symptoms]		.M="Missing" .N="Not Applicable" 1="Mild" 2="Moderate" 3="Severe"
basesymptom_none	Check Here If None Reported (No Baseline Symptoms) - [Baseline Symptoms]		.M="Missing" 1="None"
basesymptom_onset_dt1-4	Onset Date For Symptom [X] - [Baseline Symptoms]		SAS Date .M="Missing" .N="Not Applicable"

Section 10: Baseline Medical/Surgical History

Variable	Label	Description	Format Text
basehist_allergies_specify	If Yes (Allergies), Specify - [Baseline Medical/Surgical History]		Char, 191
basehist_any_allergies	Does The Participant Have Any Allergies? - [Baseline Medical/Surgical History]		.M="Missing" 0="No" 1="Yes"
basehist_breasts_abn	Has Breast Abnormality? - [Baseline Medical/Surgical History]		.N="Not Applicable" .R="Participant Not Randomized" 0="No" 9="Not Assessed"
basehist_breasts_comments	Comments On Condition/Diagnosis For Breast - [Baseline Medical/Surgical History]		Char, 973
basehist_cardio_abn	Has Cardiovascular Abnormality? - [Baseline Medical/Surgical History]		.N="Not Applicable" .R="Participant Not Randomized" 0="No" 1="Yes"
basehist_cardio_comments	Comments On Condition/Diagnosis For Cardiovascular - [Baseline Medical/Surgical History]		Char, 973
basehist_derm_abn	Has Dermatologic Abnormality? - [Baseline Medical/Surgical History]		.N="Not Applicable" .R="Participant Not Randomized" 0="No" 1="Yes"
basehist_derm_comments	Comments On Condition/Diagnosis For Dermatologic - [Baseline Medical/Surgical History]		Char, 973
basehist_endo_abn	Has Endocrine/Metabolic Abnormality? - [Baseline Medical/Surgical History]		.N="Not Applicable" .R="Participant Not Randomized" 0="No" 1="Yes"
basehist_endo_comments	Comments On Condition/Diagnosis For Endocrine/Metabolic - [Baseline Medical/Surgical History]		Char, 973
basehist_gast_abn	Has Gastrointestinal Abnormality? - [Baseline Medical/Surgical History]		.N="Not Applicable" .R="Participant Not Randomized" 0="No" 1="Yes"
basehist_gast_comments	Comments On Condition/Diagnosis For Gastrointestinal - [Baseline Medical/Surgical History]		Char, 973

Variable	Label	Description	Format Text
basehist_genit_abn	Has Genitourinary Abnormality? - [Baseline Medical/Surgical History]		.N="Not Applicable" .R="Participant Not Randomized" 1="Yes"
basehist_genit_comments	Comments On Condition/Diagnosis For Genitourinary - [Baseline Medical/Surgical History]		Char, 973
basehist_heent_abn	Has H/E/E/N/T Abnormality? - [Baseline Medical/Surgical History]		.M="Missing" .R="Participant Not Randomized" 0="No" 1="Yes"
basehist_heent_comments	Comments On Condition/Diagnosis For H/E/E/N/T - [Baseline Medical/Surgical History]		Char, 973
basehist_hema_abn	Has Hematopoietic/Lymph Abnormality? - [Baseline Medical/Surgical History]		.N="Not Applicable" .R="Participant Not Randomized" 0="No" 1="Yes"
basehist_hema_comments	Comments On Condition/Diagnosis For Hematopoietic/Lymph - [Baseline Medical/Surgical History]		Char, 973
basehist_musc_abn	Has Musculoskeletal Abnormality? - [Baseline Medical/Surgical History]		.N="Not Applicable" .R="Participant Not Randomized" 0="No" 1="Yes"
basehist_musc_comments	Comments On Condition/Diagnosis For Musculoskeletal - [Baseline Medical/Surgical History]		Char, 973
basehist_neck_abn	Has Neck Abnormality? - [Baseline Medical/Surgical History]		.N="Not Applicable" .R="Participant Not Randomized" 0="No" 1="Yes"
basehist_neck_comments	Comments On Condition/Diagnosis For Neck - [Baseline Medical/Surgical History]		Char, 973
basehist_neur_abn	Has Neurologic Abnormality? - [Baseline Medical/Surgical History]		.N="Not Applicable" .R="Participant Not Randomized" 0="No" 1="Yes"
basehist_neur_comments	Comments On Condition/Diagnosis For Neurologic - [Baseline Medical/Surgical History]		Char, 973
basehist_other_abn	Has Other Abnormality - [Baseline Medical/Surgical History]		.F="No Form" .M="Missing" .R="Participant Not Randomized" 1="Yes"
basehist_other_body_system	Other Body System - [Baseline Medical/Surgical History]		Char, 11

Variable	Label	Description	Format Text
basehist_other_comments	Other Body System Comments - [Baseline Medical/Surgical History]		Char, 48
basehist_resp_abn	Has Respiratory Abnormality? - [Baseline Medical/Surgical History]		.N="Not Applicable" .R="Participant Not Randomized" 0="No" 1="Yes"
basehist_resp_comments	Comments On Condition/Diagnosis For Respiratory - [Baseline Medical/Surgical History]		Char, 973

Section 11: Randomization

Variable	Label	Description	Format Text
rand_dt	Randomization Date - [Randomization]		SAS Date .R="Participant Not Randomized"
rand_num	Randomization Number - [Randomization]		Numeric .R="Participant Not Randomized"

Section 12: Intervention

Variable	Label	Description	Format Text
intervention_provided_dt	Date Agent Provided - [Intervention Administration]		SAS Date .M="Missing" .R="Participant Not Randomized"
intervention_started_dt	Date Agent Started - [Intervention Administration]		SAS Date .M="Missing" .R="Participant Not Randomized"

Section 13: Concomitant Medications

Variable	Label	Description	Format Text
conmed_cnt	Number Of Concomitant Medications - [Concomitant Medications]		Numeric
conmed_continuing1-58	Continuing Medication [X] - [Concomitant Medications]		.M="Missing" .N="Not Applicable" 0="No" 1="Yes"
conmed_dose1-58	Medication Dose [X] - [Concomitant Medications]		Numeric .M="Missing" .N="Not Applicable"
conmed_eos_none1-58	At End Of Only: Check This Box If Participant Did Not Take Any Concomitant Medications - [Concomitant Medications]		.M="Missing" .N="Not Applicable"
conmed_frequency1-58	Medication Frequency [X]- [Concomitant Medications]		Char, 11
conmed_medication1-58	Medication [X]- [Concomitant Medications]		Char, 105
conmed_medication_dt1-58	Medication Reported Date [X] - [Concomitant Medications]		SAS Date .M="Missing" .N="Not Applicable"
conmed_reason1-58	Medication Reason [X] - [Concomitant Medications]		Char, 71
conmed_start_dt1-58	Medication Start Date [X] - [Concomitant Medications]		SAS Date .M="Missing" .N="Not Applicable"
conmed_stop_dt1-58	Medication Stop Date [X]- [Concomitant Medications]		SAS Date .M="Missing" .N="Not Applicable"
conmed_units1-58	Medication Units [X] - [Concomitant Medications]		Char, 12

Section 14: Agent Interruption

Variable	Label	Description	Format Text
agentint_cnt	Number Of Interruptions - [Agent Interruption]		Numeric .F="No Form" .R="Participant Not Randomized"
agentint_reason_stopped1-43	Reason Stopped For Interruption [X] - [Agent Interruption]		.F="No Form" .M="Missing" .N="Not Applicable" .R="Participant Not Randomized" 2="Participant decision, specify" 3="AE/SAE, specify" 4="Other, specify"
agentint_spec_dt_restarted1-43	If Yes, Specify Date Restarted For Interruption [X] - [Agent Interruption]		SAS Date .F="No Form" .M="Missing" .N="Not Applicable" .R="Participant Not Randomized"
agentint_spec_dt_stopped1-43	Specify Date Stopped For Interruption [X] - [Agent Interruption]		SAS Date .F="No Form" .M="Missing" .N="Not Applicable" .R="Participant Not Randomized"
agentint_spec_reason_restarted1-43	Specify Reason Restarted For Interruption [X] - [Agent Interruption]		.F="No Form" .M="Missing" .N="Not Applicable" .R="Participant Not Randomized" 2="Participant decision"
agentint_spec_reason_stopped1-43	Specify Reason Stopped For Interruption [X] - [Agent Interruption]		Char, 239
agentint_was_agent_restarted1-43	Was Agent Restarted For Interruption [X] - [Agent Interruption]		.F="No Form" .M="Missing" .N="Not Applicable" .R="Participant Not Randomized" 0="No" 1="Yes"

Section 15: Adverse Events Summary

Variable	Label	Description	Format Text
aes_ae	Patient Had AE - [Adverse Events Summary]		.F="No Form" .R="Participant Not Randomized" 0="No" 1="Yes"
aes_attribution	Maximum Attribution Of AE For Patient - [Adverse Events Summary]		.F="No Form" .R="Participant Not Randomized" 0="No Event" 1="Possible" 2="Probable" 3="Unlikely" 4="Unrelated"
aes_max_severity	Maximum Severity Of AE For Patient - [Adverse Events Summary]		.F="No Form" .R="Participant Not Randomized" 0="Mild" 1="Moderate" 2="No Event" 3="Severe"
aes_multiple	Patient Had Multiple AEs - [Adverse Events Summary]		.F="No Form" .R="Participant Not Randomized" 0="No" 1="Yes"
aes_num	Number Of AEs - [Adverse Events Summary]		Numeric .F="No Form" .R="Participant Not Randomized"
aes_num_cat	Categorized Number Of AEs - [Adverse Events Summary]		Numeric .F="No Form" .R="Participant Not Randomized"
aes_sae	Patient Had SAE - [Adverse Events Summary]		.F="No Form" .R="Participant Not Randomized" 0="No" 1="Yes"
aes_severity	Patient Had Severe AE - [Adverse Events Summary]		.F="No Form" .R="Participant Not Randomized" 0="No" 1="Yes"

Section 16: Compliance

Variable	Label	Description	Format Text
compliance_amt_missing_v1-4	Amount Of Agent Missing/Not Accounted For This Period At Visit [X] - [Compliance]	Each Visit Represents A Period Of Time: Visit 1 = Week 13 to Week 25 Visit 2 = Week 26 to Week 38 Visit 3 = Week 39 to Week 51 Visit 4 = Week 52	Numeric .F="No Form" .R="Participant Not Randomized"
compliance_amt_provided_last_v1-4	Amount Of Agent Provided At Last Visit At Visit [X] - [Compliance]		Numeric .F="No Form" .M="Missing" .R="Participant Not Randomized"
compliance_amt_provided_v1-4	Amount Of Agent Provided At Visit [X] - [Compliance]		Numeric .F="No Form" .M="Missing" .R="Participant Not Randomized"
compliance_amt_returned_v1-4	Amount Of Agent Returned At Visit [X] - [Compliance]		Numeric .F="No Form" .R="Participant Not Randomized"
compliance_amt_taken_v1-4	Amount Of Agent Taken During This Period At Visit [X] - [Compliance]	Each Visit Represents A Period Of Time: Visit 1 = Week 13 to Week 25 Visit 2 = Week 26 to Week 38 Visit 3 = Week 39 to Week 51 Visit 4 = Week 52	Numeric .F="No Form" .R="Participant Not Randomized"
compliance_first_dose_dt_v1-4	Date First Dose Was Taken This Period At Visit [X] - [Compliance]	Each Visit Represents A Period Of Time: Visit 1 = Week 13 to Week 25 Visit 2 = Week 26 to Week 38 Visit 3 = Week 39 to Week 51 Visit 4 = Week 52	SAS Date .F="No Form" .R="Participant Not Randomized"
compliance_first_dose_time_v1-4	Time First Dose Was Taken This Period At Visit [X] - [Compliance]	Each Visit Represents A Period Of Time: Visit 1 = Week 13 to Week 25 Visit 2 = Week 26 to Week 38 Visit 3 = Week 39 to Week 51 Visit 4 = Week 52	SAS Time .F="No Form" .R="Participant Not Randomized"

Variable	Label	Description	Format Text
compliance_interrupted_v1-4	Was Agent Interrupted This Period At Visit [X]? - [Compliance]	Each Visit Represents A Period Of Time: Visit 1 = Week 13 to Week 25 Visit 2 = Week 26 to Week 38 Visit 3 = Week 39 to Week 51 Visit 4 = Week 52	.F="No Form" .R="Participant Not Randomized" 0="No" 1="Yes" 9="Unknown"
compliance_last_dose_dt_v1-4	Date Last Dose Was Taken This Period At Visit [X] - [Compliance]	Each Visit Represents A Period Of Time: Visit 1 = Week 13 to Week 25 Visit 2 = Week 26 to Week 38 Visit 3 = Week 39 to Week 51 Visit 4 = Week 52	SAS Date .F="No Form" .R="Participant Not Randomized"
compliance_last_dose_time_v1-4	Time Last Dose Was Taken This Period At Visit [X] - [Compliance]	Each Visit Represents A Period Of Time: Visit 1 = Week 13 to Week 25 Visit 2 = Week 26 to Week 38 Visit 3 = Week 39 to Week 51 Visit 4 = Week 52	SAS Time .F="No Form" .R="Participant Not Randomized"
compliance_noncompliance_v1-4	Specify Reason For Noncompliance At Visit [X] - [Compliance]		Char, 612
compliance_num_interrupt_v1-4	Indicate The Number Of Interruptions This Period At Visit [X] - [Compliance]	Each Visit Represents A Period Of Time: Visit 1 = Week 13 to Week 25 Visit 2 = Week 26 to Week 38 Visit 3 = Week 39 to Week 51 Visit 4 = Week 52	Numeric .F="No Form" .M="Missing" .R="Participant Not Randomized"
compliance_protocol_v1-4	Is The Participant Compliant With The Protocol Intervention At Visit [X] - [Compliance]		.F="No Form" .R="Participant Not Randomized" 1="Yes"
compliance_provided_v1-4	Was Agent Provided At Visit [X] - [Compliance]		.F="No Form" .R="Participant Not Randomized" 0="No" 1="Yes"
compliance_regimen_mod_v1-4	Was Agent Regimen Modified During This Period At Visit [X]? - [Compliance]	Each Visit Represents A Period Of Time: Visit 1 = Week 13 to Week 25 Visit 2 = Week 26 to Week 38 Visit 3 = Week 39 to Week 51 Visit 4 = Week 52	.F="No Form" .R="Participant Not Randomized" 0="No"

Section 17: Comments

Variable	Label	Description	Format Text
comment_comments	Comments - [Comments]		char, 856
comments_formcode	Form Code - [Comments]		.F="No Form" .R="Participant Not Randomized" 1="PE1"

Section 18: Verification

Variable	Label	Description	Format Text
verification_form_dt	Form Date - [Verification]		SAS Date
verification_inv_sig	Investigator's Signature - [Verification]		Numeric
verification_inv_sig_dt	Date Of Investigator's Signature - [Verification]		SAS Date

Section 19: Offstudy

Variable	Label	Description	Format Text
offstudy_agent_end_dt	Agent End Date - [Off Study]		SAS Date .M="Missing"
offstudy_dt	Off Study Date - [Off Study]		SAS Date
offstudy_form_dt	Form Date - [Off Study]		SAS Date
offstudy_last_contact_dt	Date Of Last Contact - [Off Study]		SAS Date
offstudy_reason	Reason Off Study - [Off Study]		1="Study Complete" 5="Participant Withdrawal" 6="Ineligible"
offstudy_reason_explain	Reason Explanation - [Off Study]		Char, 308

Section 20: Clinical Laboratory Data Blood Chemistry

Variable	Label	Description	Format Text
clinblood_alkaline_comment_v0-4	Comments At Visit [X] - Alkaline Phosphatase - [Clinical Laboratory Data Blood Chemistry]		Char, 307
clinblood_alkaline_notob_v0-4	Not Obtained At Visit [X] - Alkaline Phosphatase - [Clinical Laboratory Data Blood Chemistry]		Numeric .F="No Form" .M="Missing"
clinblood_alkaline_oor_v0-4	Out of Range At Visit [X] - Alkaline Phosphatase - [Clinical Laboratory Data Blood Chemistry]		Numeric .F="No Form"
clinblood_alkaline_result_v0-4	Result At Visit [X] - Alkaline Phosphatase - [Clinical Laboratory Data Blood Chemistry]		Numeric .F="No Form"
clinblood_alkaline_sig_v0-4	Clinically Significant At Visit [X] - Alkaline Phosphatase - [Clinical Laboratory Data Blood Chemistry]		.F="No Form" 0="No"
clinblood_alkaline_unit_v0-4	Units At Visit [X] - Alkaline Phosphatase - [Clinical Laboratory Data Blood Chemistry]		Numeric .F="No Form"
clinblood_alt_comment_v0-4	Comments At Visit [X] - ALT - [Clinical Laboratory Data Blood Chemistry]		Char, 307
clinblood_alt_notob_v0-4	Not Obtained At Visit [X] - ALT - [Clinical Laboratory Data Blood Chemistry]		Numeric .F="No Form" .M="Missing"
clinblood_alt_oor_v0-4	Out of Range At Visit [X] - ALT - [Clinical Laboratory Data Blood Chemistry]		Numeric .F="No Form"
clinblood_alt_result_v0-4	Result At Visit [X] - ALT - [Clinical Laboratory Data Blood Chemistry]		Numeric .F="No Form"
clinblood_alt_sig_v0-4	Clinically Significant At Visit [X] - ALT - [Clinical Laboratory Data Blood Chemistry]		.F="No Form" 0="No"
clinblood_alt_unit_v0-4	Units At Visit [X] - ALT - [Clinical Laboratory Data Blood Chemistry]		Numeric .F="No Form"
clinblood_ast_comment_v0-4	Comments At Visit [X] - AST - [Clinical Laboratory Data Blood Chemistry]		Char, 307

Variable	Label	Description	Format Text
clinblood_ast_notob_v0-4	Not Obtained At Visit [X] - AST - [Clinical Laboratory Data Blood Chemistry]		Numeric .F="No Form" .M="Missing"
clinblood_ast_oor_v0-4	Out of Range At Visit [X] - AST - [Clinical Laboratory Data Blood Chemistry]		Numeric .F="No Form"
clinblood_ast_result_v0-4	Result At Visit [X] - AST - [Clinical Laboratory Data Blood Chemistry]		Numeric .F="No Form"
clinblood_ast_sig_v0-4	Clinically Significant At Visit [X] - AST - [Clinical Laboratory Data Blood Chemistry]		.F="No Form" 0="No"
clinblood_ast_unit_v0-4	Units At Visit [X] - AST - [Clinical Laboratory Data Blood Chemistry]		Numeric .F="No Form"
clinblood_bicarbonate_comment_v0-4	Comments At Visit [X] - Bicarbonate - [Clinical Laboratory Data Blood Chemistry]		Char, 307
clinblood_bicarbonate_notob_v0-4	Not Obtained At Visit [X] - Bicarbonate - [Clinical Laboratory Data Blood Chemistry]		Numeric .F="No Form" .M="Missing"
clinblood_bicarbonate_oor_v0-4	Out of Range At Visit [X] - Bicarbonate - [Clinical Laboratory Data Blood Chemistry]		Numeric .F="No Form"
clinblood_bicarbonate_result_v0-4	Result At Visit [X] - Bicarbonate - [Clinical Laboratory Data Blood Chemistry]		Numeric .F="No Form"
clinblood_bicarbonate_sig_v0-4	Clinically Significant At Visit [X] - Bicarbonate - [Clinical Laboratory Data Blood Chemistry]		.F="No Form" 0="No"
clinblood_bicarbonate_unit_v0-4	Units At Visit [X] - Bicarbonate - [Clinical Laboratory Data Blood Chemistry]		Numeric .F="No Form"
clinblood_bilirubin_comment_v0-4	Comments At Visit [X] - Bilirubin (Total) - [Clinical Laboratory Data Blood Chemistry]		Char, 307
clinblood_bilirubin_notob_v0-4	Not Obtained At Visit [X] - Bilirubin (Total) - [Clinical Laboratory Data Blood Chemistry]		Numeric .F="No Form" .M="Missing"
clinblood_bilirubin_oor_v0-4	Out of Range At Visit [X] - Bilirubin (Total) - [Clinical Laboratory Data Blood Chemistry]		Numeric .F="No Form"

Variable	Label	Description	Format Text
clinblood_bilirubin_result_v0-4	Result At Visit [X] - Bilirubin (Total) - [Clinical Laboratory Data Blood Chemistry]		Numeric .F="No Form"
clinblood_bilirubin_sig_v0-4	Clinically Significant At Visit [X] - Bilirubin (Total) - [Clinical Laboratory Data Blood Chemistry]		.F="No Form" 0="No"
clinblood_bilirubin_unit_v0-4	Units At Visit [X] - Bilirubin (Total) - [Clinical Laboratory Data Blood Chemistry]		Numeric .F="No Form"
clinblood_chloride_comment_v0-4	Comments At Visit [X] - Chloride - [Clinical Laboratory Data Blood Chemistry]		Char, 307
clinblood_chloride_notob_v0-4	Not Obtained At Visit [X] - Chloride - [Clinical Laboratory Data Blood Chemistry]		Numeric .F="No Form" .M="Missing"
clinblood_chloride_oor_v0-4	Out of Range At Visit [X] - Chloride - [Clinical Laboratory Data Blood Chemistry]		Numeric .F="No Form"
clinblood_chloride_result_v0-4	Result At Visit [X] - Chloride - [Clinical Laboratory Data Blood Chemistry]		Numeric .F="No Form"
clinblood_chloride_sig_v0-4	Clinically Significant At Visit [X] - Chloride - [Clinical Laboratory Data Blood Chemistry]		.F="No Form" 0="No"
clinblood_chloride_unit_v0-4	Units At Visit [X] - Chloride - [Clinical Laboratory Data Blood Chemistry]		Numeric .F="No Form"
clinblood_fasting_v0-4	Fasting At Visit [X] - [Clinical Laboratory Data Blood Chemistry]		Numeric .F="No Form" .N="Not Applicable"
clinblood_potassium_comment2_v0	Comments At Visit 0 (Baseline) (2nd) - Potassium - [Clinical Laboratory Data Blood Chemistry]		Char, 307
clinblood_potassium_comment_v0-4	Comments At Visit [X] - Potassium - [Clinical Laboratory Data Blood Chemistry]		Char, 307
clinblood_potassium_notob2_v0	Not Obtained At Visit 0 (Baseline) (2nd) - Potassium - [Clinical Laboratory Data Blood Chemistry]		Numeric .F="No Form"

Variable	Label	Description	Format Text
clinblood_potassiu m_notob_v0-4	Not Obtained At Visit [X] - Potassium - [Clinical Laboratory Data Blood Chemistry]		Numeric .F="No Form" .M="Missing"
clinblood_potassiu m_oor2_v0	Out of Range At Visit 0 (Baseline) (2nd) - Potassium - [Clinical Laboratory Data Blood Chemistry]		Numeric .F="No Form"
clinblood_potassiu m_oor_v0-4	Out of Range At Visit [X] - Potassium - [Clinical Laboratory Data Blood Chemistry]		Numeric .F="No Form"
clinblood_potassiu m_result2_v0	Result At Visit 0 (Baseline) (2nd) - Potassium - [Clinical Laboratory Data Blood Chemistry]		Numeric .F="No Form"
clinblood_potassiu m_result_v0-4	Result At Visit [X] - Potassium - [Clinical Laboratory Data Blood Chemistry]		Numeric .F="No Form"
clinblood_potassiu m_sig2_v0	Clinically Significant At Visit 0 (Baseline) (2nd) - Potassium - [Clinical Laboratory Data Blood Chemistry]		.F="No Form"
clinblood_potassiu m_sig_v0-4	Clinically Significant At Visit [X] - Potassium - [Clinical Laboratory Data Blood Chemistry]		.F="No Form" 0="No"
clinblood_potassiu m_unit2_v0	Units At Visit 0 (Baseline) (2nd) - Potassium - [Clinical Laboratory Data Blood Chemistry]		Numeric .F="No Form"
clinblood_potassiu m_unit_v0-4	Units At Visit [X] - Potassium - [Clinical Laboratory Data Blood Chemistry]		Numeric .F="No Form"
clinblood_psa_com ment_v0-4	Comments At Visit [X] - PSA - [Clinical Laboratory Data Blood Chemistry]		Char, 307
clinblood_psa_noto b_v0-4	Not Obtained At Visit [X] - PSA - [Clinical Laboratory Data Blood Chemistry]		Numeric .F="No Form" .M="Missing"
clinblood_psa_oor_ v0-4	Out of Range At Visit [X] - PSA - [Clinical Laboratory Data Blood Chemistry]		Numeric .F="No Form"
clinblood_psa_resul t_v0-4	Result At Visit [X] - PSA - [Clinical Laboratory Data Blood Chemistry]		Numeric .F="No Form"
clinblood_psa_sig_ v0-4	Clinically Significant At Visit [X] - PSA - [Clinical Laboratory Data Blood Chemistry]		.F="No Form" .N="Not Applicable" 0="No" 1="Yes"

Variable	Label	Description	Format Text
clinblood_psa_unit_v0-4	Units At Visit [X] - PSA - [Clinical Laboratory Data Blood Chemistry]		Numeric .F="No Form"
clinblood_serum_comment_v0-4	Comments At Visit [X] - Serum Creatinine - [Clinical Laboratory Data Blood Chemistry]		Char, 307
clinblood_serum_notob_v0-4	Not Obtained At Visit [X] - Serum Creatinine - [Clinical Laboratory Data Blood Chemistry]		Numeric .F="No Form" .M="Missing"
clinblood_serum_or_v0-4	Out of Range At Visit [X] - Serum Creatinine - [Clinical Laboratory Data Blood Chemistry]		Numeric .F="No Form"
clinblood_serum_result_v0-4	Result At Visit [X] - Serum Creatinine - [Clinical Laboratory Data Blood Chemistry]		Numeric .F="No Form"
clinblood_serum_sig_v0-4	Clinically Significant At Visit [X] - Serum Creatinine - [Clinical Laboratory Data Blood Chemistry]		.F="No Form" 0="No" 1="Yes"
clinblood_serum_unit_v0-4	Units At Visit [X] - Serum Creatinine - [Clinical Laboratory Data Blood Chemistry]		Numeric .F="No Form"
clinblood_sodium_comment2_v0	Comments At Visit 0 (Baseline) (2nd) - Sodium - [Clinical Laboratory Data Blood Chemistry]		Char, 307
clinblood_sodium_comment_v0-4	Comments At Visit [X] - Sodium - [Clinical Laboratory Data Blood Chemistry]		Char, 307
clinblood_sodium_notob2_v0	Not Obtained At Visit 0 (Baseline) (2nd) - Sodium - [Clinical Laboratory Data Blood Chemistry]		Numeric .F="No Form"
clinblood_sodium_notob_v0-4	Not Obtained At Visit [X] - Sodium - [Clinical Laboratory Data Blood Chemistry]		Numeric .F="No Form" .M="Missing"
clinblood_sodium_or2_v0	Out of Range At Visit 0 (Baseline) (2nd) - Sodium - [Clinical Laboratory Data Blood Chemistry]		Numeric .F="No Form"
clinblood_sodium_or_v0-4	Out of Range At Visit [X] - Sodium - [Clinical Laboratory Data Blood Chemistry]		Numeric .F="No Form"
clinblood_sodium_result2_v0	Result At Visit 0 (Baseline) (2nd) - Sodium - [Clinical Laboratory Data Blood Chemistry]		Numeric .F="No Form"

Variable	Label	Description	Format Text
clinblood_sodium_result_v0-4	Result At Visit [X] - Sodium - [Clinical Laboratory Data Blood Chemistry]		Numeric .F="No Form"
clinblood_sodium_sig2_v0	Clinically Significant At Visit 0 (Baseline) (2nd) - Sodium - [Clinical Laboratory Data Blood Chemistry]		.F="No Form"
clinblood_sodium_sig_v0-4	Clinically Significant At Visit [X] - Sodium - [Clinical Laboratory Data Blood Chemistry]		.F="No Form" 0="No"
clinblood_sodium_unit2_v0	Units At Visit 0 (Baseline) (2nd) - Sodium - [Clinical Laboratory Data Blood Chemistry]		Numeric .F="No Form"
clinblood_sodium_unit_v0-4	Units At Visit [X] - Sodium - [Clinical Laboratory Data Blood Chemistry]		Numeric .F="No Form"

Section 21: Clinical Laboratory Data Hematology

Variable	Label	Description	Format Text
clinhema_hemoglob_in_comment_v0-4	Hemoglobin Comment At Visit [X] - [Clinical Laboratory Data Hematology]		Char, 135
clinhema_hemoglob_in_oor_v0-4	Hemoglobin At Visit [X] - Out Of Range - [Clinical Laboratory Data Hematology]		.F="No Form" .M="Missing" 0="No" 1="Yes"
clinhema_hemoglob_in_result_v0-4	Hemoglobin At Visit [X] - Result - [Clinical Laboratory Data Hematology]		Numeric .F="No Form" .M="Missing"
clinhema_hemoglob_in_sig_v0-4	Hemoglobin Clinically Significant At Visit [X] - [Clinical Laboratory Data Hematology]		.F="No Form" .M="Missing" 0="No"
clinhema_hemoglob_in_unit_v0-4	Hemoglobin At Visit [X] - Units - [Clinical Laboratory Data Hematology]		.F="No Form" .M="Missing" 1="K/uL" 2="g/dL"
clinhema_platelets_comment_v0-4	Platelets Comment At Visit [X] - [Clinical Laboratory Data Hematology]		Char, 135
clinhema_platelets_in_oor_v0-4	Platelets At Visit [X] - Out Of Range - [Clinical Laboratory Data Hematology]		.F="No Form" 0="No" 1="Yes"
clinhema_platelets_in_result_v0-4	Platelets At Visit [X] - Result - [Clinical Laboratory Data Hematology]		Numeric .F="No Form"
clinhema_platelets_in_sig_v0-4	Platelets Clinically Significant At Visit [X] - [Clinical Laboratory Data Hematology]		.F="No Form" 0="No"
clinhema_platelets_in_unit_v0-4	Platelets At Visit [X] - Units - [Clinical Laboratory Data Hematology]		.F="No Form" 1="K/uL"
clinhema_wbc_comment_v0-4	White Blood Cells Comment At Visit [X] - [Clinical Laboratory Data Hematology]		Char, 135
clinhema_wbc_in_oor_v0-4	White Blood Cells At Visit [X] - Out Of Range - [Clinical Laboratory Data Hematology]		.F="No Form" 0="No" 1="Yes"

Variable	Label	Description	Format Text
clinhema_wbc_result_v0-4	White Blood Cells At Visit [X] - Result - [Clinical Laboratory Data Hematology]		Numeric .F="No Form"
clinhema_wbc_sig_v0-4	White Blood Cells Clinically Significant At Visit [X] - [Clinical Laboratory Data Hematology]		.F="No Form" 0="No"
clinhema_wbc_unit_v0-4	White Blood Cells At Visit [X] - Units - [Clinical Laboratory Data Hematology]		.F="No Form" 1="K/uL"

Section 22: Specimen Acquisition Blood

Variable	Label	Description	Format Text
specacqblood_dt_last_taken_v0-4	Date Last Study Agent Taken At Visit [X] - [Specimen Acquisition Blood]		SAS Date .F="No Form" .M="Missing" .N="Not Applicable"
specacqblood_dt_spec_collect_v0-4	Date Specimen Collected At Visit [X] - [Specimen Acquisition Blood]		SAS Date .F="No Form" .M="Missing"
specacqblood_dt_spec_ship_v0-4	Date Specimen Shipped At Visit [X] - [Specimen Acquisition Blood]		SAS Date .F="No Form" .M="Missing"
specacqblood_storage_v0-4	Storage Temperature At Visit [X] (Centigrade) - [Specimen Acquisition Blood]		Numeric .F="No Form" .M="Missing"
specacqblood_time_last_taken_v0-4	Time last Study Agent Taken At Visit [X] (hr:mm per 24 hr clock) - [Specimen Acquisition Blood]		SAS Time .F="No Form" .M="Missing"
specacqblood_time_spec_collec_v0-4	Time Specimen Collected At Visit [X] (hr:mm per 24 hr clock) - [Specimen Acquisition Blood]		SAS Time .F="No Form" .M="Missing"

Section 23: Specimen Acquisition Urine

Variable	Label	Description	Format Text
specacqurine_dt_la st_taken_v0-4	Date Last Study Agent Taken At Visit [X] - [Specimen Acquisition Urine]		SAS Date .F="No Form" .M="Missing"
specacqurine_dt_sp ec_collect_v0-4	Date Specimen Collected At Visit [X] - [Specimen Acquisition Urine]		SAS Date .F="No Form" .M="Missing"
specacqurine_NO_v 0-4	Not Obtained At Visit [X] - [Specimen Acquisition Urine]		Numeric .F="No Form" .M="Missing"
specacqurine_spec _ship_dt_v0-4	Date Specimen Shipped At Visit [X] - [Specimen Acquisition Urine]		SAS Date .F="No Form" .M="Missing"
specacqurine_stora ge_temp_v0-4	Storage Temperature At Visit [X] - [Specimen Acquisition Urine]		Numeric .F="No Form" .M="Missing"
specacqurine_time_ last_taken_v0-4	Time Last Study Agent Taken At Visit [X] (hr:mm per 24 hr clock) - [Specimen Acquisition Urine]		SAS Time .F="No Form" .M="Missing"
specacqurine_time_ spec_coll_v0-4	Time Specimen Collected At Visit [X] (hr:mm per 24 hr clock) - [Specimen Acquisition Urine]		SAS Time .F="No Form" .M="Missing"

Section 24: Specimen Acquisition Tissue

Variable	Label	Description	Format Text
specacqtissue_biopsy_dt_eos	Date Of Biopsy - End Of Study - [Specimen Acquisition Urine]		SAS Date .M="Missing"
specacqtissue_biopsy_dt_pre	Date Of Biopsy - Pre-Study - [Specimen Acquisition Urine]		SAS Date .M="Missing"
specacqtissue_gleason_score_eos	Gleason Score - End Of Study - [Specimen Acquisition Urine]		Char, 5
specacqtissue_gleason_score_pre	Gleason Score - Pre-Study - [Specimen Acquisition Urine]		Char, 5
specacqtissue_last_dose_dt	Date Last Dose Prior To Biopsy - [Specimen Acquisition Urine]		SAS Date .M="Missing"
specacqtissue_last_dose_time	Time Last Dose Prior To Biopsy (hr:mm per 24 hr clock) - [Specimen Acquisition Urine]		SAS Time .M="Missing"

Section 25: Biopsy

Variable	Label	Description	Format Text
biopsy_cxstg_v0	Cx Stage - Visit 0 (Baseline) - [Biopsy]		.F="No Form" .N="Not Applicable" .R="Participant Not Randomized" 1="PSA Elevated, Not Palpable, Found In Needle Biopsy"
biopsy_cxstg_v4	Cx Stage - Visit 4 (End Of Study) - [Biopsy]		.F="No Form" .N="Not Applicable" .R="Participant Not Randomized"
biopsy_gdiff_v4	Gleason Score Diff From Baseline (If Applicable) - Visit 4 (End Of Study) - [Biopsy]		Numeric .F="No Form" .N="Not Applicable" .R="Participant Not Randomized"
biopsy_gleastxt_v0	Gleason Score (Text) - Visit 0 (Baseline) - [Biopsy]		"3+3"="3+3"
biopsy_gleastxt_v4	Gleason Score (Text) - Visit 4 (End Of Study) - [Biopsy]		"3+3"="3+3" "3+4"="3+4"
biopsy_gscore_v0	Gleason Score - Visit 0 (Baseline) - [Biopsy]		Numeric .F="No Form" .N="Not Applicable" .R="Participant Not Randomized"
biopsy_gscore_v4	Gleason Score - Visit 4 (End Of Study) - [Biopsy]		Numeric .F="No Form" .N="Not Applicable" .R="Participant Not Randomized"
biopsy_location_v0	Location Of Tissue - Visit 0 (Baseline) - [Biopsy]		.F="No Form" .N="Not Applicable" .R="Participant Not Randomized" 8="R Apex"
biopsy_location_v4	Location Of Tissue - Visit 4 (End Of Study) - [Biopsy]		.F="No Form" .M="Missing" .N="Not Applicable" .R="Participant Not Randomized" 1="L Apex" 2="L Base" 4="L Lat Ba" 5="L Lat Mi" 6="L Mid" 8="R Apex" 11="R Lat ap" 12="R Mid"
biopsy_mcore_v0	Max Core Involvement (Percent) - Visit 0 (Baseline) - [Biopsy]		Numeric .F="No Form" .N="Not Applicable" .R="Participant Not Randomized"
biopsy_mcore_v4	Max Core Involvement (Percent) - Visit 4 (End Of Study) - [Biopsy]		Numeric .F="No Form" .N="Not Applicable" .R="Participant Not Randomized"

Variable	Label	Description	Format Text
biopsy_ncores_v0	Number Of Cores Involved - Visit 0 (Baseline) - [Biopsy]		Numeric .F="No Form" .N="Not Applicable" .R="Participant Not Randomized"
biopsy_ncores_v4	Number Of Cores Involved - Visit 4 (End Of Study) - [Biopsy]		Numeric .F="No Form" .N="Not Applicable" .R="Participant Not Randomized"
biopsy_szinv_v0	Size/Involvement - Visit 0 (Baseline) - [Biopsy]		Char, 70
biopsy_szinv_v4	Size/Involvement - Visit 4 (End Of Study) - [Biopsy]		Char, 70
biopsy_tcores_v0	Number Of Total Cores - Visit 0 (Baseline) - [Biopsy]		Numeric .F="No Form" .N="Not Applicable" .R="Participant Not Randomized"
biopsy_tcores_v4	Number Of Total Cores - Visit 4 (End Of Study) - [Biopsy]		Numeric .F="No Form" .N="Not Applicable" .R="Participant Not Randomized"
biopsy_ttv0_v0	Total Tumor Volume (mm) - Visit 0 (Baseline) - [Biopsy]		Numeric .F="No Form" .N="Not Applicable" .R="Participant Not Randomized"
biopsy_ttv0_v4	Total Tumor Volume (mm) - Visit 4 (End Of Study) - [Biopsy]		Numeric .F="No Form" .N="Not Applicable" .R="Participant Not Randomized"

Section 26: Abnormal Lab Test

Variable	Label	Description	Format Text
ablab_alk_phos_abn	Alkaline Phosphatase - Abnormal At Any Time - [Abnormal Lab Test]		.F="No Form" .R="Participant Not Randomized" 0="No" 1="Yes"
ablab_bicarb_abn	Bicarbonate - Abnormal At Any Time - [Abnormal Lab Test]		.F="No Form" .R="Participant Not Randomized" 0="No" 1="Yes"
ablab_bilirubin_abn	Bilirubin, Total - Abnormal At Any Time - [Abnormal Lab Test]		.F="No Form" .R="Participant Not Randomized" 0="No" 1="Yes"
ablab_chloride_abn	Chloride - Abnormal At Any Time - [Abnormal Lab Test]		.F="No Form" .R="Participant Not Randomized" 0="No" 1="Yes"
ablab_creatinine_abn	Creatinine, Serum - Abnormal At Any Time - [Abnormal Lab Test]		.F="No Form" .R="Participant Not Randomized" 0="No" 1="Yes"
ablab_hemoglobin_abn	Hemoglobin - Abnormal At Any Time - [Abnormal Lab Test]		.F="No Form" .R="Participant Not Randomized" 0="No" 1="Yes"
ablab_platelets_abn	Platelets - Abnormal At Any Time - [Abnormal Lab Test]		.F="No Form" .R="Participant Not Randomized" 0="No" 1="Yes"
ablab_potassium_abn	Potassium - Abnormal At Any Time - [Abnormal Lab Test]		.F="No Form" .R="Participant Not Randomized" 0="No" 1="Yes"
ablab_psa_abn	PSA - Abnormal At Any Time - [Abnormal Lab Test]		.F="No Form" .R="Participant Not Randomized" 0="No" 1="Yes"
ablab_sgot_abn	SGOT/AST - Abnormal At Any Time - [Abnormal Lab Test]		.F="No Form" .R="Participant Not Randomized" 0="No" 1="Yes"
ablab_sgpt_abn	SGPT/ALT - Abnormal At Any Time - [Abnormal Lab Test]		.F="No Form" .R="Participant Not Randomized" 0="No" 1="Yes"
ablab_sodium_abn	Sodium - Abnormal At Any Time - [Abnormal Lab Test]		.F="No Form" .R="Participant Not Randomized" 0="No" 1="Yes"

Variable	Label	Description	Format Text
ablab_wbc_abn	White Blood Cells - Abnormal At Any Time - [Abnormal Lab Test]		.F="No Form" .R="Participant Not Randomized" 0="No" 1="Yes"

Section 27: Maximum Adverse Events

Variable	Label	Description	Format Text
cmae_maxatt_cardiac	Maximum Attribution - Cardiac Disorders - [Maximum Adverse Events]		.F="No Form" .R="Participant Not Randomized" 0="No Event" 1="Unrelated"
cmae_maxatt_ear	Maximum Attribution - Ear And labyrinth Disorders - [Maximum Adverse Events]		.F="No Form" .R="Participant Not Randomized" 0="No Event" 1="Unrelated"
cmae_maxatt_eye	Maximum Attribution - Eye Disorders - [Maximum Adverse Events]		.F="No Form" .R="Participant Not Randomized" 0="No Event" 1="Unrelated"
cmae_maxatt_gastrointestinal	Maximum Attribution - Gastrointestinal Disorders - [Maximum Adverse Events]		.F="No Form" .R="Participant Not Randomized" 0="No Event" 1="Unrelated" 2="Unlikely" 3="Possible" 4="Probable"
cmae_maxatt_general	Maximum Attribution - General Disorders And Administration Site Conditions - [Maximum Adverse Events]		.F="No Form" .R="Participant Not Randomized" 0="No Event" 1="Unrelated" 2="Unlikely"
cmae_maxatt_hepatobiliary	Maximum Attribution - Hepatobiliary Disorders - [Maximum Adverse Events]		.F="No Form" .R="Participant Not Randomized" 0="No Event" 1="Unrelated"
cmae_maxatt_immune	Maximum Attribution - Immune System Disorders - [Maximum Adverse Events]		.F="No Form" .R="Participant Not Randomized" 0="No Event" 1="Unrelated"
cmae_maxatt_infect	Maximum Attribution - Infections And Infestations - [Maximum Adverse Events]		.F="No Form" .R="Participant Not Randomized" 0="No Event" 1="Unrelated"
cmae_maxatt_injury	Maximum Attribution - Injury, Poisoning And Procedural Complications - [Maximum Adverse Events]		.F="No Form" .R="Participant Not Randomized" 0="No Event" 1="Unrelated"
cmae_maxatt_inv	Maximum Attribution - Investigations - [Maximum Adverse Events]		.F="No Form" .R="Participant Not Randomized" 0="No Event" 1="Unrelated" 2="Unlikely"
cmae_maxatt_lymph	Maximum Attribution - Blood And Lymphatic System Disorders - [Maximum Adverse Events]		.F="No Form" .R="Participant Not Randomized" 0="No Event" 1="Unrelated"

Variable	Label	Description	Format Text
cmae_maxatt_metabolism	Maximum Attribution - Metabolism And Nutrition Disorders - [Maximum Adverse Events]		.F="No Form" .R="Participant Not Randomized" 0="No Event" 1="Unrelated"
cmae_maxatt_musculoskeletal	Maximum Attribution - Musculoskeletal And Connective Tissue Disorders - [Maximum Adverse Events]		.F="No Form" .R="Participant Not Randomized" 0="No Event" 1="Unrelated" 2="Unlikely"
cmae_maxatt_neoplasms	Maximum Attribution - Neoplasms Benign, Malignant And Unspecified (Incl Cysts And Polyps) - [Maximum Adverse Events]		.F="No Form" .R="Participant Not Randomized" 0="No Event" 1="Unrelated"
cmae_maxatt_nervous	Maximum Attribution - Nervous System Disorders - [Maximum Adverse Events]		.F="No Form" .R="Participant Not Randomized" 0="No Event" 1="Unrelated" 2="Unlikely"
cmae_maxatt_overall	Maximum Attribution - Overall - [Maximum Adverse Events]		.F="No Form" .R="Participant Not Randomized" 0="No Event" 1="Unrelated" 2="Unlikely" 3="Possible" 4="Probable"
cmae_maxatt_psychiatric	Maximum Attribution - Psychiatric Disorders - [Maximum Adverse Events]		.F="No Form" .R="Participant Not Randomized" 0="No Event" 1="Unrelated"
cmae_maxatt_renal	Maximum Attribution - Renal And Urinary Disorders - [Maximum Adverse Events]		.F="No Form" .R="Participant Not Randomized" 0="No Event" 1="Unrelated" 2="Unlikely"
cmae_maxatt_reproductive	Maximum Attribution - Reproductive System And Breast Disorders - [Maximum Adverse Events]		.F="No Form" .R="Participant Not Randomized" 0="No Event" 1="Unrelated"
cmae_maxatt_respiratory	Maximum Attribution - Respiratory, Thoracic And Mediastinal Disorders - [Maximum Adverse Events]		.F="No Form" .R="Participant Not Randomized" 0="No Event" 1="Unrelated"
cmae_maxatt_skin	Maximum Attribution - Skin And Subcutaneous Tissue Disorders - [Maximum Adverse Events]		.F="No Form" .R="Participant Not Randomized" 0="No Event" 1="Unrelated" 2="Unlikely"
cmae_maxatt_surgical	Maximum Attribution - Surgical And Medical Procedures - [Maximum Adverse Events]		.F="No Form" .R="Participant Not Randomized" 0="No Event" 1="Unrelated"
cmae_maxatt_vascular	Maximum Attribution - Vascular Disorders - [Maximum Adverse Events]		.F="No Form" .R="Participant Not Randomized" 0="No Event" 1="Unrelated"

Variable	Label	Description	Format Text
cmae_maxsev_cardiac	Maximum Severity - Cardiac Disorders - [Maximum Adverse Events]		.F="No Form" .R="Participant Not Randomized" 0="No Event" 1="Mild"
cmae_maxsev_ear	Maximum Severity - Ear And labyrinth Disorders - [Maximum Adverse Events]		.F="No Form" .R="Participant Not Randomized" 0="No Event" 1="Mild"
cmae_maxsev_eye	Maximum Severity - Eye Disorders - [Maximum Adverse Events]		.F="No Form" .R="Participant Not Randomized" 0="No Event" 2="Moderate"
cmae_maxsev_gastrointestinal	Maximum Severity - Gastrointestinal Disorders - [Maximum Adverse Events]		.F="No Form" .R="Participant Not Randomized" 0="No Event" 1="Mild" 2="Moderate" 3="Severe"
cmae_maxsev_general	Maximum Severity - General Disorders And Administration Site Conditions - [Maximum Adverse Events]		.F="No Form" .R="Participant Not Randomized" 0="No Event" 1="Mild" 2="Moderate" 3="Severe"
cmae_maxsev_hepatobiliary	Maximum Severity - Hepatobiliary Disorders - [Maximum Adverse Events]		.F="No Form" .R="Participant Not Randomized" 0="No Event" 3="Severe"
cmae_maxsev_immune	Maximum Severity - Immune System Disorders - [Maximum Adverse Events]		.F="No Form" .R="Participant Not Randomized" 0="No Event" 2="Moderate"
cmae_maxsev_infect	Maximum Severity - Infections And Infestations - [Maximum Adverse Events]		.F="No Form" .R="Participant Not Randomized" 0="No Event" 2="Moderate" 3="Severe"
cmae_maxsev_injury	Maximum Severity - Injury, Poisoning And Procedural Complication - [Maximum Adverse Events]		.F="No Form" .R="Participant Not Randomized" 0="No Event" 1="Mild" 3="Severe"
cmae_maxsev_inv	Maximum Severity - Investigations - [Maximum Adverse Events]		.F="No Form" .R="Participant Not Randomized" 0="No Event" 1="Mild"
cmae_maxsev_lymph	Maximum Severity - Blood And Lymphatic System Disorders - [Maximum Adverse Events]		.F="No Form" .R="Participant Not Randomized" 0="No Event" 1="Mild"
cmae_maxsev_metabolism	Maximum Severity - Metabolism And Nutrition Disorders - [Maximum Adverse Events]		.F="No Form" .R="Participant Not Randomized" 0="No Event" 1="Mild"

Variable	Label	Description	Format Text
cmae_maxsev_musculoskeletal	Maximum Severity - Musculoskeletal And Connective Tissue Disorders - [Maximum Adverse Events]		.F="No Form" .R="Participant Not Randomized" 0="No Event" 1="Mild" 2="Moderate" 3="Severe"
cmae_maxsev_neoplasms	Maximum Severity - Neoplasms Benign, Malignant And Unspecified (Incl Cysts And Polyps) - [Maximum Adverse Events]		.F="No Form" .R="Participant Not Randomized" 0="No Event" 2="Moderate"
cmae_maxsev_nervous	Maximum Severity - Nervous System Disorders - [Maximum Adverse Events]		.F="No Form" .R="Participant Not Randomized" 0="No Event" 1="Mild" 2="Moderate"
cmae_maxsev_overall	Maximum Severity - Overall - [Maximum Adverse Events]		.F="No Form" .R="Participant Not Randomized" 0="No Event" 1="Mild" 2="Moderate" 3="Severe"
cmae_maxsev_psychiatric	Maximum Severity - Psychiatric Disorders - [Maximum Adverse Events]		.F="No Form" .R="Participant Not Randomized" 0="No Event" 1="Mild" 2="Moderate"
cmae_maxsev_renal	Maximum Severity - Renal And Urinary Disorders - [Maximum Adverse Events]		.F="No Form" .R="Participant Not Randomized" 0="No Event" 1="Mild" 2="Moderate"
cmae_maxsev_reproductive	Maximum Severity - Reproductive System And Breast Disorders - [Maximum Adverse Events]		.F="No Form" .R="Participant Not Randomized" 0="No Event" 1="Mild" 2="Moderate"
cmae_maxsev_respiratory	Maximum Severity - Respiratory, Thoracic And Mediastinal Disorders - [Maximum Adverse Events]		.F="No Form" .R="Participant Not Randomized" 0="No Event" 1="Mild" 2="Moderate"
cmae_maxsev_skin	Maximum Severity - Skin And Subcutaneous Tissue Disorders - [Maximum Adverse Events]		.F="No Form" .R="Participant Not Randomized" 0="No Event" 1="Mild" 2="Moderate"
cmae_maxsev_surgical	Maximum Severity - Surgical And Medical Procedures - [Maximum Adverse Events]		.F="No Form" .R="Participant Not Randomized" 0="No Event" 2="Moderate" 3="Severe"

Variable	Label	Description	Format Text
cmae_maxsev_vascular	Maximum Severity - Vascular Disorders - [Maximum Adverse Events]		.F="No Form" .R="Participant Not Randomized" 0="No Event" 1="Mild" 2="Moderate" 3="Severe"

Section 28: ELISA Tests

Variable	Label	Description	Format Text
elisa_freetest_v0	Free Testosterone At Visit 0 (Baseline) (pg/mL) - [Elisa]		Numeric .F="No Form" .R="Participant Not Randomized"
elisa_freetest_v2	Free Testosterone At Visit 2 (Week 26) (pg/mL) (ng/mL) - [Elisa]		Numeric .F="No Form" .R="Participant Not Randomized"
elisa_freetest_v4	Free Testosterone At Visit 4 (End Of Study) (pg/mL) (ng/mL) - [Elisa]		Numeric .F="No Form" .R="Participant Not Randomized"
elisa_ifg1_v0	IFG-1 At Visit 0 (Baseline) (ng/mL) - [Elisa]		Numeric .F="No Form" .R="Participant Not Randomized"
elisa_ifg1_v1	IFG-1 At Visit 1 (Week 13) (ng/mL) - [Elisa]		Numeric .F="No Form" .R="Participant Not Randomized"
elisa_ifg1_v2	IFG-1 At Visit 2 (Week 26) (ng/mL) - [Elisa]		Numeric .F="No Form" .R="Participant Not Randomized"
elisa_ifg1_v3	IFG-1 At Visit 3 (Week 39) (ng/mL) - [Elisa]		Numeric .F="No Form" .R="Participant Not Randomized"
elisa_ifg1_v4	IFG-1 At Visit 4 (End Of Study) (ng/mL) - [Elisa]		Numeric .F="No Form" .R="Participant Not Randomized"
elisa_igfbp3_v0	IGFBP-3 At Visit 0 (Baseline) (ng/mL) - [Elisa]		Numeric .F="No Form" .R="Participant Not Randomized"
elisa_igfbp3_v1	IGFBP-3 At Visit 1 (Week 13) (ng/mL) - [Elisa]		Numeric .F="No Form" .R="Participant Not Randomized"
elisa_igfbp3_v2	IGFBP-3 At Visit 2 (Week 26) (ng/mL) - [Elisa]		Numeric .F="No Form" .R="Participant Not Randomized"
elisa_igfbp3_v3	IGFBP-3 At Visit 3 (Week 39) (ng/mL) - [Elisa]		Numeric .F="No Form" .R="Participant Not Randomized"
elisa_igfbp3_v4	IGFBP-3 At Visit 4 (End Of Study) (ng/mL) - [Elisa]		Numeric .F="No Form" .R="Participant Not Randomized"
elisa_psa_v0	PSA At Visit 0 (Baseline) (ng/mL) - [Elisa]		Numeric .F="No Form" .R="Participant Not Randomized"
elisa_psa_v1	PSA At Visit 1 (Week 13) (ng/mL) - [Elisa]		Numeric .F="No Form" .R="Participant Not Randomized"

Variable	Label	Description	Format Text
elisa_psa_v2	PSA At Visit 2 (Week 26) (ng/mL) - [Elisa]		Numeric .F="No Form" .R="Participant Not Randomized"
elisa_psa_v3	PSA At Visit 3 (Week 39) (ng/mL) - [Elisa]		Numeric .F="No Form" .R="Participant Not Randomized"
elisa_psa_v4	PSA At Visit 4 (End Of Study) (ng/mL) - [Elisa]		Numeric .F="No Form" .R="Participant Not Randomized"
elisa_ratio_v0	IGF-1/IGFBP-3 Ratio At Visit 0 (Baseline) - [Elisa]		Numeric .F="No Form" .R="Participant Not Randomized"
elisa_ratio_v1	IGF-1/IGFBP-3 Ratio At Visit 1 (Week 13) - [Elisa]		Numeric .F="No Form" .R="Participant Not Randomized"
elisa_ratio_v2	IGF-1/IGFBP-3 Ratio At Visit 2 (Week 26) - [Elisa]		Numeric .F="No Form" .R="Participant Not Randomized"
elisa_ratio_v3	IGF-1/IGFBP-3 Ratio At Visit 3 (Week 39) - [Elisa]		Numeric .F="No Form" .R="Participant Not Randomized"
elisa_ratio_v4	IGF-1/IGFBP-3 Ratio At Visit 4 (End Of Study) - [Elisa]		Numeric .F="No Form" .R="Participant Not Randomized"

Section 29: High Performance Liquid Chromatography

Variable	Label	Description	Format Text
hplc_uroa_v0-4	UroA Conc. (ng/mL) At Visit [X] - [High Performance Liquid Chromatography]		Numeric .F="No Form" .R="Participant Not Randomized"
hplc_uroam_v0-4	UroA Metab. (ng) At Visit [X] - [High Performance Liquid Chromatography]		Numeric .F="No Form" .R="Participant Not Randomized"
hplc_urob_v0-4	UroB Conc. (ng/mL) At Visit [X] - [High Performance Liquid Chromatography]		Numeric .F="No Form" .R="Participant Not Randomized"
hplc_urobm_v0-4	UroB Metab. (ng) At Visit [X] - [High Performance Liquid Chromatography]		Numeric .F="No Form" .R="Participant Not Randomized"
hplc_urvm_v0-4	Urine Volume At Visit [X] - [High Performance Liquid Chromatography]		Numeric .F="No Form" .R="Participant Not Randomized"

Section 30: Mass Spectrometry Plasma

Variable	Label	Description	Format Text
mspl_pldimea_v0-4	Dimethyl-EA Detected In Plasma At Visit [X] - [Mass Spectrometry - Plasma]		Numeric .F="No Form" .R="Participant Not Randomized"
mspl_pldimeagl_v0-4	Dimethyl-EA Glucuronide Detected In Plasma At Visit [X] - [Mass Spectrometry - Plasma]		Numeric .F="No Form" .R="Participant Not Randomized"
mspl_plea_v0-4	Ellagic Acid Detected In Plasma At Visit [X] - [Mass Spectrometry - Plasma]		Numeric .F="No Form" .R="Participant Not Randomized"
mspl_ploa_v0-4	Urolithin A Detected In Plasma At Visit [X] - [Mass Spectrometry - Plasma]		Numeric .F="No Form" .R="Participant Not Randomized"
mspl_ploagl_v0-4	Urolithin A Glucuronide Detected In Plasma At Visit [X] - [Mass Spectrometry - Plasma]		Numeric .F="No Form" .R="Participant Not Randomized"
mspl_plob_v0-4	Urolithin B Detected In Plasma At Visit [X] - [Mass Spectrometry - Plasma]		Numeric .F="No Form" .R="Participant Not Randomized"
mspl_plobgl_v0-4	Urolithin B Glucuronide Detected In Plasma At Visit [X] - [Mass Spectrometry - Plasma]		Numeric .F="No Form" .R="Participant Not Randomized"

Section 31: Mass Spectrometry Urine

Variable	Label	Description	Format Text
msur_urdimea_v0-4	Dimethyl-EA Detected In Urine At Visit [X] - [Mass Spectrometry - Urine]		Numeric .F="No Form" .R="Participant Not Randomized"
msur_urdimeagl_v0-4	Dimethyl-EA Glucuronide Detected In Urine At Visit [X] - [Mass Spectrometry - Urine]		Numeric .F="No Form" .R="Participant Not Randomized"
msur_urea_v0-4	Ellagic Acid Detected In Urine At Visit [X] - [Mass Spectrometry - Urine]		Numeric .F="No Form" .R="Participant Not Randomized"
msur_uroa_v0-4	Urolithin A Detected In Urine At Visit [X] - [Mass Spectrometry - Urine]		Numeric .F="No Form" .R="Participant Not Randomized"
msur_uroagl_v0-4	Urolithin A Glucuronide Detected In Urine At Visit [X] - [Mass Spectrometry - Urine]		Numeric .F="No Form" .R="Participant Not Randomized"
msur_urob_v0-4	Urolithin B Detected In Urine At Visit [X] - [Mass Spectrometry - Urine]		Numeric .F="No Form" .R="Participant Not Randomized"
msur_uroagl_v0-4	Urolithin B Glucuronide Detected In Urine At Visit [X] - [Mass Spectrometry - Urine]		Numeric .F="No Form" .R="Participant Not Randomized"

Section 32: Tissue IHC Biomarkers 1

Variable	Label	Description	Format Text
pom1b_bpt_ccas3_v0	Cytoplasm Caspase-3 (Normalized Mean Optical Density) - BPT Result At Visit 0 (Baseline) - [Tissue IHC Biomarkers 1]		Numeric .F="No Form" .R="Participant Not Randomized"
pom1b_bpt_ccas3_v4	Cytoplasm Caspase-3 (Normalized Mean Optical Density) - BPT Result At Visit 4 (End Of Study) - [Tissue IHC Biomarkers 1]		Numeric .F="No Form" .R="Participant Not Randomized"
pom1b_bpt_ecas3_v0	Entire Cell Caspase-3 (Normalized Mean Optical Density) - BPT Result At Visit 0 (Baseline) - [Tissue IHC Biomarkers 1]		Numeric .F="No Form" .R="Participant Not Randomized"
pom1b_bpt_ecas3_v4	Entire Cell Caspase-3 (Normalized Mean Optical Density) - BPT Result At Visit 4 (End Of Study) - [Tissue IHC Biomarkers 1]		Numeric .F="No Form" .R="Participant Not Randomized"
pom1b_bpt_k67_v0	Ki67 (Mean Percent) - BPT Result At Visit 0 (Baseline) - [Tissue IHC Biomarkers 1]		Numeric .F="No Form" .R="Participant Not Randomized"
pom1b_bpt_k67_v4	Ki67 (Mean Percent) - BPT Result At Visit 4 (End Of Study) - [Tissue IHC Biomarkers 1]		Numeric .F="No Form" .R="Participant Not Randomized"
pom1b_bpt_ncas3_v0	Nucleus Caspase-3 (Normalized Mean Optical Density) - BPT Result At Visit 0 (Baseline) - [Tissue IHC Biomarkers 1]		Numeric .F="No Form" .R="Participant Not Randomized"
pom1b_bpt_ncas3_v4	Nucleus Caspase-3 (Normalized Mean Optical Density) - BPT Result At Visit 4 (End Of Study) - [Tissue IHC Biomarkers 1]		Numeric .F="No Form" .R="Participant Not Randomized"
pom1b_bptadj_ccas3_v0	Cytoplasm Caspase-3 (Normalized Mean Optical Density) - Adjacent BPT Result At Visit 0 (Baseline) - [Tissue IHC Biomarkers 1]		Numeric .F="No Form" .R="Participant Not Randomized"
pom1b_bptadj_ccas3_v4	Cytoplasm Caspase-3 (Normalized Mean Optical Density) - Adjacent BPT Result At Visit 4 (End Of Study) - [Tissue IHC Biomarkers 1]		Numeric .F="No Form" .R="Participant Not Randomized"

Variable	Label	Description	Format Text
pom1b_bptadj_ecas3_v0	Entire Cell Caspase-3 (Normalized Mean Optical Density) - Adjacent BPT Result At Visit 0 (Baseline) - [Tissue IHC Biomarkers 1]		Numeric .F="No Form" .R="Participant Not Randomized"
pom1b_bptadj_ecas3_v4	Entire Cell Caspase-3 (Normalized Mean Optical Density) - Adjacent BPT Result At Visit 4 (End Of Study) - [Tissue IHC Biomarkers 1]		Numeric .F="No Form" .R="Participant Not Randomized"
pom1b_bptadj_k67_v0	Ki67 (Mean Percent) - Adjacent BPT Result At Visit 0 (Baseline) - [Tissue IHC Biomarkers 1]		Numeric .F="No Form" .R="Participant Not Randomized"
pom1b_bptadj_k67_v4	Ki67 (Mean Percent) - Adjacent BPT Result At Visit 4 (End Of Study) - [Tissue IHC Biomarkers 1]		Numeric .F="No Form" .R="Participant Not Randomized"
pom1b_bptadj_ncas3_v0	Nucleus Caspase-3 (Normalized Mean Optical Density) - Adjacent BPT Result At Visit 0 (Baseline) - [Tissue IHC Biomarkers 1]		Numeric .F="No Form" .R="Participant Not Randomized"
pom1b_bptadj_ncas3_v4	Nucleus Caspase-3 (Normalized Mean Optical Density) - Adjacent BPT Result At Visit 4 (End Of Study) - [Tissue IHC Biomarkers 1]		Numeric .F="No Form" .R="Participant Not Randomized"
pom1b_pca_ccas3_v0	Cytoplasm Caspase-3 (Normalized Mean Optical Density) - PCa Result At Visit 0 (Baseline) - [Tissue IHC Biomarkers 1]		Numeric .F="No Form" .R="Participant Not Randomized"
pom1b_pca_ccas3_v4	Cytoplasm Caspase-3 (Normalized Mean Optical Density) - PCa Result At Visit 4 (End Of Study) - [Tissue IHC Biomarkers 1]		Numeric .F="No Form" .R="Participant Not Randomized"
pom1b_pca_ecas3_v0	Entire Cell Caspase-3 (Normalized Mean Optical Density) - PCa Result At Visit 0 (Baseline) - [Tissue IHC Biomarkers 1]		Numeric .F="No Form" .R="Participant Not Randomized"
pom1b_pca_ecas3_v4	Entire Cell Caspase-3 (Normalized Mean Optical Density) - PCa Result At Visit 4 (End Of Study) - [Tissue IHC Biomarkers 1]		Numeric .F="No Form" .R="Participant Not Randomized"
pom1b_pca_k67_v0	Ki67 (Mean Percent) - PCa Result At Visit 0 (Baseline) - [Tissue IHC Biomarkers 1]		Numeric .F="No Form" .R="Participant Not Randomized"

Variable	Label	Description	Format Text
pom1b_pca_k67_v4	Ki67 (Mean Percent) - PCa Result At Visit 4 (End Of Study) - [Tissue IHC Biomarkers 1]		Numeric .F="No Form" .R="Participant Not Randomized"
pom1b_pca_ncas3_v0	Nucleus Caspase-3 (Normalized Mean Optical Density) - PCa Result At Visit 0 (Baseline) - [Tissue IHC Biomarkers 1]		Numeric .F="No Form" .R="Participant Not Randomized"
pom1b_pca_ncas3_v4	Nucleus Caspase-3 (Normalized Mean Optical Density) - PCa Result At Visit 4 (End Of Study) - [Tissue IHC Biomarkers 1]		Numeric .F="No Form" .R="Participant Not Randomized"

Section 33: Tissue IHC Biomarkers 2

Variable	Label	Description	Format Text
pom2b_bpt_c8hdg_v0	Cytoplasm 8-Hdg (Normalized Mean Optical Density) - BPT Result At Visit 0 (Baseline) - [Tissue IHC Biomarkers 2]		Numeric .F="No Form" .R="Participant Not Randomized"
pom2b_bpt_c8hdg_v4	Cytoplasm 8-Hdg (Normalized Mean Optical Density) - BPT Result At Visit 4 (End Of Study) - [Tissue IHC Biomarkers 2]		Numeric .F="No Form" .R="Participant Not Randomized"
pom2b_bpt_cigf1_v0	Cytoplasm IGF-1 (Normalized Mean Optical Density) - BPT Result At Visit 0 (Baseline) - [Tissue IHC Biomarkers 2]		Numeric .F="No Form" .R="Participant Not Randomized"
pom2b_bpt_cigf1_v4	Cytoplasm IGF-1 (Normalized Mean Optical Density) - BPT Result At Visit 4 (End Of Study) - [Tissue IHC Biomarkers 2]		Numeric .F="No Form" .R="Participant Not Randomized"
pom2b_bpt_e8hdg_v0	Entire Cell 8-Hdg (Normalized Mean Optical Density) - BPT Result At Visit 0 (Baseline) - [Tissue IHC Biomarkers 2]		Numeric .F="No Form" .R="Participant Not Randomized"
pom2b_bpt_e8hdg_v4	Entire Cell 8-Hdg (Normalized Mean Optical Density) - BPT Result At Visit 4 (End Of Study) - [Tissue IHC Biomarkers 2]		Numeric .F="No Form" .R="Participant Not Randomized"
pom2b_bpt_eigf1_v0	Entire Cell IGF-1 (Normalized Mean Optical Density) - BPT Result At Visit 0 (Baseline) - [Tissue IHC Biomarkers 2]		Numeric .F="No Form" .R="Participant Not Randomized"
pom2b_bpt_eigf1_v4	Entire Cell IGF-1 (Normalized Mean Optical Density) - BPT Result At Visit 4 (End Of Study) - [Tissue IHC Biomarkers 2]		Numeric .F="No Form" .R="Participant Not Randomized"
pom2b_bpt_n8hdg_v0	Nucleus 8-Hdg (Normalized Mean Optical Density) - BPT Result At Visit 0 (Baseline) - [Tissue IHC Biomarkers 2]		Numeric .F="No Form" .R="Participant Not Randomized"
pom2b_bpt_n8hdg_v4	Nucleus 8-Hdg (Normalized Mean Optical Density) - BPT Result At Visit 4 (End Of Study) - [Tissue IHC Biomarkers 2]		Numeric .F="No Form" .R="Participant Not Randomized"

Variable	Label	Description	Format Text
pom2b_bpt_nigf1_v0	Nucleus IGF-1 (Normalized Mean Optical Density) - BPT Result At Visit 0 (Baseline) - [Tissue IHC Biomarkers 2]		Numeric .F="No Form" .R="Participant Not Randomized"
pom2b_bpt_nigf1_v4	Nucleus IGF-1 (Normalized Mean Optical Density) - BPT Result At Visit 4 (End Of Study) - [Tissue IHC Biomarkers 2]		Numeric .F="No Form" .R="Participant Not Randomized"
pom2b_bptadj_c8hdg_v0	Cytoplasm 8-Hdg (Normalized Mean Optical Density) - Adjacent BPT Result At Visit 0 (Baseline) - [Tissue IHC Biomarkers 2]		Numeric .F="No Form" .R="Participant Not Randomized"
pom2b_bptadj_c8hdg_v4	Cytoplasm 8-Hdg (Normalized Mean Optical Density) - Adjacent BPT Result At Visit 4 (End Of Study) - [Tissue IHC Biomarkers 2]		Numeric .F="No Form" .R="Participant Not Randomized"
pom2b_bptadj_cigf1_v0	Cytoplasm IGF-1 (Normalized Mean Optical Density) - Adjacent BPT Result At Visit 0 (Baseline) - [Tissue IHC Biomarkers 2]		Numeric .F="No Form" .R="Participant Not Randomized"
pom2b_bptadj_cigf1_v4	Cytoplasm IGF-1 (Normalized Mean Optical Density) - Adjacent BPT Result At Visit 4 (End Of Study) - [Tissue IHC Biomarkers 2]		Numeric .F="No Form" .R="Participant Not Randomized"
pom2b_bptadj_e8hdg_v0	Entire Cell 8-Hdg (Normalized Mean Optical Density) - Adjacent BPT Result At Visit 0 (Baseline) - [Tissue IHC Biomarkers 2]		Numeric .F="No Form" .R="Participant Not Randomized"
pom2b_bptadj_e8hdg_v4	Entire Cell 8-Hdg (Normalized Mean Optical Density) - Adjacent BPT Result At Visit 4 (End Of Study) - [Tissue IHC Biomarkers 2]		Numeric .F="No Form" .R="Participant Not Randomized"
pom2b_bptadj_eigf1_v0	Entire Cell IGF-1 (Normalized Mean Optical Density) - Adjacent BPT Result At Visit 0 (Baseline) - [Tissue IHC Biomarkers 2]		Numeric .F="No Form" .R="Participant Not Randomized"

Variable	Label	Description	Format Text
pom2b_bptadj_eigf1_v4	Entire Cell IGF-1 (Normalized Mean Optical Density) - Adjacent BPT Result At Visit 4 (End Of Study) - [Tissue IHC Biomarkers 2]		Numeric .F="No Form" .R="Participant Not Randomized"
pom2b_bptadj_n8hdg_v0	Nucleus 8-Hdg (Normalized Mean Optical Density) - Adjacent BPT Result At Visit 0 (Baseline) - [Tissue IHC Biomarkers 2]		Numeric .F="No Form" .R="Participant Not Randomized"
pom2b_bptadj_n8hdg_v4	Nucleus 8-Hdg (Normalized Mean Optical Density) - Adjacent BPT Result At Visit 4 (End Of Study) - [Tissue IHC Biomarkers 2]		Numeric .F="No Form" .R="Participant Not Randomized"
pom2b_bptadj_nigf1_v0	Nucleus IGF-1 (Normalized Mean Optical Density) - Adjacent BPT Result At Visit 0 (Baseline) - [Tissue IHC Biomarkers 2]		Numeric .F="No Form" .R="Participant Not Randomized"
pom2b_bptadj_nigf1_v4	Nucleus IGF-1 (Normalized Mean Optical Density) - Adjacent BPT Result At Visit 4 (End Of Study) - [Tissue IHC Biomarkers 2]		Numeric .F="No Form" .R="Participant Not Randomized"
pom2b_pca_c8hdg_v0	Cytoplasm 8-Hdg (Normalized Mean Optical Density) - BPT Result At Visit 0 (Baseline) - [Tissue IHC Biomarkers 2]		Numeric .F="No Form" .R="Participant Not Randomized"
pom2b_pca_c8hdg_v4	Cytoplasm 8-Hdg (Normalized Mean Optical Density) - BPT Result At Visit 4 (End Of Study) - [Tissue IHC Biomarkers 2]		Numeric .F="No Form" .R="Participant Not Randomized"
pom2b_pca_cigf1_v0	Cytoplasm IGF-1 (Normalized Mean Optical Density) - PCa Result At Visit 0 (Baseline) - [Tissue IHC Biomarkers 2]		Numeric .F="No Form" .R="Participant Not Randomized"
pom2b_pca_cigf1_v4	Cytoplasm IGF-1 (Normalized Mean Optical Density) - PCa Result At Visit 4 (End Of Study) - [Tissue IHC Biomarkers 2]		Numeric .F="No Form" .R="Participant Not Randomized"
pom2b_pca_e8hdg_v0	Entire Cell 8-Hdg (Normalized Mean Optical Density) - PCa Result At Visit 0 (Baseline) - [Tissue IHC Biomarkers 2]		Numeric .F="No Form" .R="Participant Not Randomized"

Variable	Label	Description	Format Text
pom2b_pca_e8hdg_v4	Entire Cell 8-Hdg (Normalized Mean Optical Density) - PCa Result At Visit 4 (End Of Study) - [Tissue IHC Biomarkers 2]		Numeric .F="No Form" .R="Participant Not Randomized"
pom2b_pca_eigf1_v0	Entire Cell IGF-1 (Normalized Mean Optical Density) - PCa Result At Visit 0 (Baseline) - [Tissue IHC Biomarkers 2]		Numeric .F="No Form" .R="Participant Not Randomized"
pom2b_pca_eigf1_v4	Entire Cell IGF-1 (Normalized Mean Optical Density) - PCa Result At Visit 4 (End Of Study) - [Tissue IHC Biomarkers 2]		Numeric .F="No Form" .R="Participant Not Randomized"
pom2b_pca_n8hdg_v0	Nucleus 8-Hdg (Normalized Mean Optical Density) - PCa Result At Visit 0 (Baseline) - [Tissue IHC Biomarkers 2]		Numeric .F="No Form" .R="Participant Not Randomized"
pom2b_pca_n8hdg_v4	Nucleus 8-Hdg (Normalized Mean Optical Density) - PCa Result At Visit 4 (End Of Study) - [Tissue IHC Biomarkers 2]		Numeric .F="No Form" .R="Participant Not Randomized"
pom2b_pca_nigf1_v0	Nucleus IGF-1 (Normalized Mean Optical Density) - PCa Result At Visit 0 (Baseline) - [Tissue IHC Biomarkers 2]		Numeric .F="No Form" .R="Participant Not Randomized"
pom2b_pca_nigf1_v4	Nucleus IGF-1 (Normalized Mean Optical Density) - PCa Result At Visit 4 (End Of Study) - [Tissue IHC Biomarkers 2]		Numeric .F="No Form" .R="Participant Not Randomized"

Section 34: Tissue IHC Biomarkers 3

Variable	Label	Description	Format Text
pom3b_bpt_cigfrb_v0	Cytoplasm IGF-Rb (Normalized Mean Optical Density) - BPT Result At Visit 0 (Baseline) - [Tissue IHC Biomarkers 3]		Numeric .F="No Form" .R="Participant Not Randomized"
pom3b_bpt_cigfrb_v4	Cytoplasm IGF-Rb (Normalized Mean Optical Density) - BPT Result At Visit 4 (End Of Study) - [Tissue IHC Biomarkers 3]		Numeric .F="No Form" .R="Participant Not Randomized"
pom3b_bpt_eigfrb_v0	Entire Cell IGF-Rb (Normalized Mean Optical Density) - BPT Result At Visit 0 (Baseline) - [Tissue IHC Biomarkers 3]		Numeric .F="No Form" .R="Participant Not Randomized"
pom3b_bpt_eigfrb_v4	Entire Cell IGF-Rb (Normalized Mean Optical Density) - BPT Result At Visit 4 (End Of Study) - [Tissue IHC Biomarkers 3]		Numeric .F="No Form" .R="Participant Not Randomized"
pom3b_bpt_nar_v0	Nucleus AR (Normalized Mean Optical Density) - BPT Result At Visit 0 (Baseline) - [Tissue IHC Biomarkers 3]		Numeric .F="No Form" .R="Participant Not Randomized"
pom3b_bpt_nar_v4	Nucleus AR (Normalized Mean Optical Density) - BPT Result At Visit 4 (End Of Study) - [Tissue IHC Biomarkers 3]		Numeric .F="No Form" .R="Participant Not Randomized"
pom3b_bpt_nigfrb_v0	Nucleus IGF-Rb (Normalized Mean Optical Density) - BPT Result At Visit 0 (Baseline) - [Tissue IHC Biomarkers 3]		Numeric .F="No Form" .R="Participant Not Randomized"
pom3b_bpt_nigfrb_v4	Nucleus IGF-Rb (Normalized Mean Optical Density) - BPT Result At Visit 4 (End Of Study) - [Tissue IHC Biomarkers 3]		Numeric .F="No Form" .R="Participant Not Randomized"
pom3b_bptadj_cigfrb_v0	Cytoplasm IGF-Rb (Normalized Mean Optical Density) - Adjacent BPT Result At Visit 0 (Baseline) - [Tissue IHC Biomarkers 3]		Numeric .F="No Form" .R="Participant Not Randomized"

Variable	Label	Description	Format Text
pom3b_bptadj_cigfr_b_v4	Cytoplasm IGF-Rb (Normalized Mean Optical Density) - Adjacent BPT Result At Visit 4 (End Of Study) - [Tissue IHC Biomarkers 3]		Numeric .F="No Form" .R="Participant Not Randomized"
pom3b_bptadj_eigfr_b_v0	Entire Cell IGF-Rb (Normalized Mean Optical Density) - Adjacent BPT Result At Visit 0 (Baseline) - [Tissue IHC Biomarkers 3]		Numeric .F="No Form" .R="Participant Not Randomized"
pom3b_bptadj_eigfr_b_v4	Entire Cell IGF-Rb (Normalized Mean Optical Density) - Adjacent BPT Result At Visit 4 (End Of Study) - [Tissue IHC Biomarkers 3]		Numeric .F="No Form" .R="Participant Not Randomized"
pom3b_bptadj_nar_v0	Nucleus AR (Normalized Mean Optical Density) - Adjacent BPT Result At Visit 0 (Baseline) - [Tissue IHC Biomarkers 3]		Numeric .F="No Form" .R="Participant Not Randomized"
pom3b_bptadj_nar_v4	Nucleus AR (Normalized Mean Optical Density) - Adjacent BPT Result At Visit 4 (End Of Study) - [Tissue IHC Biomarkers 3]		Numeric .F="No Form" .R="Participant Not Randomized"
pom3b_bptadj_nigfr_b_v0	Nucleus IGF-Rb (Normalized Mean Optical Density) - Adjacent BPT Result At Visit 0 (Baseline) - [Tissue IHC Biomarkers 3]		Numeric .F="No Form" .R="Participant Not Randomized"
pom3b_bptadj_nigfr_b_v4	Nucleus IGF-Rb (Normalized Mean Optical Density) - Adjacent BPT Result At Visit 4 (End Of Study) - [Tissue IHC Biomarkers 3]		Numeric .F="No Form" .R="Participant Not Randomized"
pom3b_pca_cigfrb_v0	Cytoplasm IGF-Rb (Normalized Mean Optical Density) - PCa Result At Visit 0 (Baseline) - [Tissue IHC Biomarkers 3]		Numeric .F="No Form" .R="Participant Not Randomized"
pom3b_pca_cigfrb_v4	Cytoplasm IGF-Rb (Normalized Mean Optical Density) - PCa Result At Visit 4 (End Of Study) - [Tissue IHC Biomarkers 3]		Numeric .F="No Form" .R="Participant Not Randomized"
pom3b_pca_eigfrb_v0	Entire Cell IGF-Rb (Normalized Mean Optical Density) - PCa Result At Visit 0 (Baseline) - [Tissue IHC Biomarkers 3]		Numeric .F="No Form" .R="Participant Not Randomized"

Variable	Label	Description	Format Text
pom3b_pca_eigfrb_v4	Entire Cell IGF-Rb (Normalized Mean Optical Density) - PCa Result At Visit 4 (End Of Study) - [Tissue IHC Biomarkers 3]		Numeric .F="No Form" .R="Participant Not Randomized"
pom3b_pca_nar_v0	Nucleus AR (Normalized Mean Optical Density) - PCa Result At Visit 0 (Baseline) - [Tissue IHC Biomarkers 3]		Numeric .F="No Form" .R="Participant Not Randomized"
pom3b_pca_nar_v4	Nucleus AR (Normalized Mean Optical Density) - PCa Result At Visit 4 (End Of Study) - [Tissue IHC Biomarkers 3]		Numeric .F="No Form" .R="Participant Not Randomized"
pom3b_pca_nigfrb_v0	Nucleus IGF-Rb (Normalized Mean Optical Density) - PCa Result At Visit 0 (Baseline) - [Tissue IHC Biomarkers 3]		Numeric .F="No Form" .R="Participant Not Randomized"
pom3b_pca_nigfrb_v4	Nucleus IGF-Rb (Normalized Mean Optical Density) - PCa Result At Visit 4 (End Of Study) - [Tissue IHC Biomarkers 3]		Numeric .F="No Form" .R="Participant Not Randomized"

Section 35: Tissue IHC Biomarkers 4

Variable	Label	Description	Format Text
pom4b_bpt_cgfbp3_v0	Cytoplasm IGFBP3 (Normalized Mean Optical Density) - BPT Result At Visit 0 (Baseline) - [Tissue IHC Biomarkers 4]		Numeric .F="No Form" .R="Participant Not Randomized"
pom4b_bpt_cgfbp3_v4	Cytoplasm IGFBP3 (Normalized Mean Optical Density) - BPT Result At Visit 4 (End Of Study) - [Tissue IHC Biomarkers 4]		Numeric .F="No Form" .R="Participant Not Randomized"
pom4b_bpt_cpsa_v0	Cytoplasm PSA (Normalized Mean Optical Density) - BPT Result At Visit 0 (Baseline) - [Tissue IHC Biomarkers 4]		Numeric .F="No Form" .R="Participant Not Randomized"
pom4b_bpt_cpsa_v4	Cytoplasm PSA (Normalized Mean Optical Density) - BPT Result At Visit 4 (End Of Study) - [Tissue IHC Biomarkers 4]		Numeric .F="No Form" .R="Participant Not Randomized"
pom4b_bpt_egfbp3_v0	Entire Cell IGFBP3 (Normalized Mean Optical Density) - BPT Result At Visit 0 (Baseline) - [Tissue IHC Biomarkers 4]		Numeric .F="No Form" .R="Participant Not Randomized"
pom4b_bpt_egfbp3_v4	Entire Cell IGFBP3 (Normalized Mean Optical Density) - BPT Result At Visit 4 (End Of Study) - [Tissue IHC Biomarkers 4]		Numeric .F="No Form" .R="Participant Not Randomized"
pom4b_bpt_ngfbp3_v0	Nucleus IGFBP3 (Normalized Mean Optical Density) - BPT Result At Visit 0 (Baseline) - [Tissue IHC Biomarkers 4]		Numeric .F="No Form" .R="Participant Not Randomized"
pom4b_bpt_ngfbp3_v4	Nucleus IGFBP3 (Normalized Mean Optical Density) - BPT Result At Visit 4 (End Of Study) - [Tissue IHC Biomarkers 4]		Numeric .F="No Form" .R="Participant Not Randomized"
pom4b_bptadj_cgfbp3_v0	Cytoplasm IGFBP3 (Normalized Mean Optical Density) - Adjacent BPT Result At Visit 0 (Baseline) - [Tissue IHC Biomarkers 4]		Numeric .F="No Form" .R="Participant Not Randomized"

Variable	Label	Description	Format Text
pom4b_bptadj_cgfbp3_v4	Cytoplasm IGFBP3 (Normalized Mean Optical Density) - Adjacent BPT Result At Visit 4 (End Of Study) - [Tissue IHC Biomarkers 4]		Numeric .F="No Form" .R="Participant Not Randomized"
pom4b_bptadj_cpsa_v0	Cytoplasm PSA (Normalized Mean Optical Density) - Adjacent BPT Result At Visit 0 (Baseline) - [Tissue IHC Biomarkers 4]		Numeric .F="No Form" .R="Participant Not Randomized"
pom4b_bptadj_cpsa_v4	Cytoplasm PSA (Normalized Mean Optical Density) - Adjacent BPT Result At Visit 4 (End Of Study) - [Tissue IHC Biomarkers 4]		Numeric .F="No Form" .R="Participant Not Randomized"
pom4b_bptadj_egfbp3_v0	Entire Cell IGFBP3 (Normalized Mean Optical Density) - Adjacent BPT Result At Visit 0 (Baseline) - [Tissue IHC Biomarkers 4]		Numeric .F="No Form" .R="Participant Not Randomized"
pom4b_bptadj_egfbp3_v4	Entire Cell IGFBP3 (Normalized Mean Optical Density) - Adjacent BPT Result At Visit 4 (End Of Study) - [Tissue IHC Biomarkers 4]		Numeric .F="No Form" .R="Participant Not Randomized"
pom4b_bptadj_ngfbp3_v0	Nucleus IGFBP3 (Normalized Mean Optical Density) - Adjacent BPT Result At Visit 0 (Baseline) - [Tissue IHC Biomarkers 4]		Numeric .F="No Form" .R="Participant Not Randomized"
pom4b_bptadj_ngfbp3_v4	Nucleus IGFBP3 (Normalized Mean Optical Density) - Adjacent BPT Result At Visit 4 (End Of Study) - [Tissue IHC Biomarkers 4]		Numeric .F="No Form" .R="Participant Not Randomized"
pom4b_pca_cgfbp3_v0	Cytoplasm IGFBP3 (Normalized Mean Optical Density) - PCa Result At Visit 0 (Baseline) - [Tissue IHC Biomarkers 4]		Numeric .F="No Form" .R="Participant Not Randomized"
pom4b_pca_cgfbp3_v4	Cytoplasm IGFBP3 (Normalized Mean Optical Density) - PCa Result At Visit 4 (End Of Study) - [Tissue IHC Biomarkers 4]		Numeric .F="No Form" .R="Participant Not Randomized"
pom4b_pca_cpsa_v0	Cytoplasm PSA (Normalized Mean Optical Density) - PCa Result At Visit 0 (Baseline) - [Tissue IHC Biomarkers 4]		Numeric .F="No Form" .R="Participant Not Randomized"

Variable	Label	Description	Format Text
pom4b_pca_cpsa_v4	Cytoplasm PSA (Normalized Mean Optical Density) - PCa Result At Visit 4 (End Of Study) - [Tissue IHC Biomarkers 4]		Numeric .F="No Form" .R="Participant Not Randomized"
pom4b_pca_egfbp3_v0	Entire Cell IGFBP3 (Normalized Mean Optical Density) - PCa Result At Visit 0 (Baseline) - [Tissue IHC Biomarkers 4]		Numeric .F="No Form" .R="Participant Not Randomized"
pom4b_pca_egfbp3_v4	Entire Cell IGFBP3 (Normalized Mean Optical Density) - PCa Result At Visit 4 (End Of Study) - [Tissue IHC Biomarkers 4]		Numeric .F="No Form" .R="Participant Not Randomized"
pom4b_pca_ngfbp3_v0	Nucleus IGFBP3 (Normalized Mean Optical Density) - PCa Result At Visit 0 (Baseline) - [Tissue IHC Biomarkers 4]		Numeric .F="No Form" .R="Participant Not Randomized"
pom4b_pca_ngfbp3_v4	Nucleus IGFBP3 (Normalized Mean Optical Density) - PCa Result At Visit 4 (End Of Study) - [Tissue IHC Biomarkers 4]		Numeric .F="No Form" .R="Participant Not Randomized"

Section 36: PSA Doubling Time

Variable	Label	Description	Format Text
psaset_aslope	Doubling Time Using Last 3 PSAs - [PSA Doubling Time]		Numeric .F="No Form" .R="Participant Not Randomized"